Exhibit 51

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
	Civil No. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	HON ROBERT B. KUGLER

****

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Continued Remote Videotaped via Zoom Deposition of MIN LI, Ph.D., commencing at 7:08 a.m. China Standard Time, on the 22nd of April, 2021, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

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Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked Highly Confidential
PAGE LINE
None.

P R O C E E D I N G S

THE VIDEOGRAPHER: We're now on the record.

My name is Judy Diaz. I am a legal videographer for Golkow Litigation Services.

Today's date is April 22, 2021, and the time is 7:08 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation MDL.

This is the continuation of the deponent Min Li Ph.D.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Maureen Pollard.

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MIN LI, Ph.D.,
having been previously duly remotely sworn, was examined and testified further as follows:

MR. SLATER: Cheryll, I think we can put up Exhibit 315, the next exhibit, and I think there's an English translation you can put in the box for counsel.
(Whereupon, Exhibit Numbers ZHP-315 and ZHP-315-t were marked for identification.)
MR. SLATER: Is it possible to make that a little smaller? Let's get that so we can see it.
FURTHER EXAMINATION
BY MR. SLATER:
Q. In front of us we have Exhibit 315, which is a July 22, 2018, e-mail.
And if we could, let's look, first of all, just at who it's written from and to. Can you just let us know what that

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says, please, in terms of who it's written from and to?
A. I don't know this person X.W. Guo. But I certainly know they're recipients, Chinese name Huang Luning, he is the vice president at SynCores.
Q. I missed who you said. Who was the person who received it?
A. Huang Luning.
Q. And he's the head of SynCores?
A. No, he is the vice president of SynCores.
Q. The vice president of SynCores.
So this e-mail was sent from the vice president of Shanghai SynCores --
A. No, I'm sorry. I don't know who the sender is, okay. That's, you know, you know, you know, like Guo, I don't know who this person. But the recipient I know. I personally know him, yes.
Q. So the recipient is the vice president of SynCores.
A. Yes.
Q. And it was written, according

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to the e-mail, by somebody who also worked at SynCores, correct?
A. Yes, looks like, yeah.
Q. And tell us, let's start with the introduction part, what that says.
A. He said, "Dr. Huang, updated the data as shown below." It said, starting from the number 6, like big points, or he said that, you know, you can look from the number 6, which is the major, you know, points, like they have like, you know, one, two, three, you know, like a big points, right. So number 6.
Q. Before you read 6, I just wanted to establish, so -- rephrase.
So this e-mail was written to Mr. Huang, and it says that an updated table is shown, and he's starting from heading number 6, it looks like, right?
A. Yes, exactly, yep.
Q. Let's look at -- first, it says in the first one, I see a 111.4 ppm. What is that referring to?
A. Just basic, you know, you know,

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what is written here, right. So first, you know, three characters is basically the Chinese name for valsartan. We call it (Chinese pronunciation valsartan), right?
So there's a parentheses, 111.4 ppm, and the next thing he said, you know, genotoxic, probably, you know, means NDMA. Okay.
So my guess is, okay, just based upon, you know, you know, what I can look at here, he probably referred to a particular valsartan batch which has NDMA, you know, in terms of its contents, like an 111.4 ppm.
Q. I wanted to see if we could go through and just understand how we calculate something. And maybe you can help me. I want to try to convert ppm to nanograms.
So if we have 111.4 ppm, my understanding is that we would then need to know the milligrams of the pill as part of the calculation, is that correct?
A. Yeah, you can certainly calculate based upon 111.4, yeah.

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Q. So it was a 320-milligram valsartan pill and it was 111.4 ppm, would we just multiply 111.4 times 320 to find the nanograms?
A. This would be in the unit also of the milligram, right? So, yeah, so 320 times 111.4, you will get -- you have to divide it by 1 million, right, divide it by 1 million, and then the number you got should be in the unit of milligram.
Q. Well, it's my understanding there's 1 million nanograms in a milligram, is that correct?
A. Well, ppm basically means 1 particle per million. It doesn't matter, like, yeah, what the -- you know, you know, it's a ratio.
Q. So if it's -- rephrase.
If it's measured in parts per million --
A. Right. So, yeah, basically if you wanted to know, you know, equivalent to 320 milligram a tablet, right, made from dispatch, so I think the calculation would be

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320 times 111.4 divided by 1 million.
And then you've got, you know, like, whatever the XYZ number, right, but the unit will be milligram, because you're starting from 320 milligram.
Q. Well, I'm trying to calculate in nanograms.
A. Nanograms, then you will be -- let's see. You will be nanograms, so milligram, micro- -- yeah, so there you will be -- let me see. You will be -- I think then you will be times 1 million again, right? So --
Q. So it would just be --
A. Yeah. Yeah. Yeah. So basically they just cancel out, then, right.
Q. So to find out how many nanograms this would be if it was a 320-milligram pill, we would multiply 111.4 times 320 to find out how many nanograms, correct?
MR. GALLAGHER: I'm going to object to this line of questioning because it's calling for expert

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testimony.
Look, it's not a math test. If you want to ask about facts and stuff, but asking him how to calculate stuff --
You can answer, Dr. Li. You should answer, to the extent you know and can.
BY MR. SLATER:
Q. Dr. Li, just because this way we'll have a basis when we ask questions later and we'll know our vocabulary, if I multiply 111.4 ppm times 320 milligram, assuming it was a 320-milligram pill, I come up with 35,648 nanograms.
That would be a correct calculation, correct?
A. I'm sorry, what is the number again that you calculated?
Q. Sure.
111.4 parts per million times 320 milligrams comes to 35,648 nanograms.
MR. GALLAGHER: Again, I'm going to object to this as calling for

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expert testimony. It's not a math test.
MR. SLATER: I think Dr. Li has a grasp on the calculation, so I'm not really sure what the objection is.
And this falls -- it helps us to answer some of the questions and the topics as we go forward.
A. It looks like so, yeah, mm-hmm.
BY MR. SLATER:
Q. Okay. So just to have a clean question and answer, the reference -- rephrase.
The reference to 111.4 ppm, if we were to assume that was in a 320-milligram valsartan pill, we would multiply 111.4 times 320 to find out how many nanograms, and here that would be 35,648, correct?
MR. GALLAGHER: Same objection.
A. Yeah, looks like so, mm-hmm.
MR. SLATER: Okay. Let's scroll down now, Cheryll, to the next part. Perfect.
BY MR. SLATER:

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Q. Looking now at Section 7, let's walk through that. It's my understanding it refers to a DMF blank experiment.

What does that mean, "a DMF blank experiment"?

A. I don't know. I mean, this is SynCores experiment. So let me read through. I will try to see whether I can have some understanding. DMF...

(Witness reviewing document.)

A. Okay. So I think, yeah, it looks like they just treated the DMF with sodium nitrite, and also like in the presence either acid or base, it looks like. Yeah, that's what -- you know, they're trying to understand how NDMA would be formed from, you know, DMF. Yeah, basically it's sort of like a part of a mechanistic study, yeah.

Q. If I understand correctly -- rephrase.

If I understand correctly, SynCores was studying the origin of how the NDMA was formed as part of a root cause investigation, correct?

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A. Looks like, yes.

MR. GALLAGHER: Objection. Lacks foundation.

BY MR. SLATER:

Q. If I understand this correctly, they indicated that as long as sodium nitrite is added, genotoxic impurities will be generated, is that correct?

A. The statement says so. And I think, you know, the genotoxic impurity here looks like, you know, from the context specific, was specifically referring to NDMA.

Q. And I think they then said -- rephrase.

And it then refers to generating this NDMA is extremely obvious in an acidic environment, is that correct?

A. Let me -- let me double-check.

Yes, looks like so. Acidic, yes, it's quite obvious, yes, was a ppm.

Q. They refer to the fact that this is caused by the additional reaction of dimethylamine. That is a degradant of DMF, correct?

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A. Yeah, the next sentence it said it should be DMF decomposition becoming dimethylamine and then reacted with sodium nitrite under condition, yes.

Q. And I think they conclude that the purpose of the experiment had been achieved, and that they can't explain that NDMA is only derived from dimethylamine in DMF because you need the sodium nitrite as stated above to create the NDMA.

Do I understand that correctly?

MR. GALLAGHER: Objection. Vague, and lacks foundation.

You can answer, Dr. Li.

A. Okay. I think -- I think the conclusion says NDMA formation, it will not only originate from the methylamine that's originally present in DMF. So based -- based upon, you know, what it says, right, from everything written here, it -- so my understanding is like under the acidic condition DMF, you know, would form -- I'm sorry, DMF would decompose to give dimethylamine.

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So at least, you know, from this experiment it seems like, you know, there -- NDMA would from, you know, two sources, right, or from two parts of the dimethylamine.

So one part of the dimethylamine would be originally present, and the other part of the dimethylamine would be, you know, decomposition product under the acidic condition, you know, or under that particular experimental condition they was performing.

BY MR. SLATER:

Q. And I think they had said -- rephrase.

They had stated above that the NDMA will be created as long as sodium nitrite is added.

Do I understand that correctly?

A. The first, the very -- after the column, right, yeah, the first sentence says, yeah, like as long as you adding sodium nitrite, yeah, it will generate NDMA.

And then the next sentence

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says, under acidic condition it will be much more obvious, yeah, like a breakdown with ppm.

And then the next one says it should be DMF, you know, decomposition.

So for everything here, it looks like, you know, the majority of the NDMA, all the dimethylamine, you know, to be converted into, you know, NDMA would be from the decomposition of DMF.

Q. Combined with the sodium nitrite?

A. Combined with sodium nitrite, yeah, under acidic conditions.

Q. And you talked yesterday about the concept of connecting the dots. This would be an example of people connecting the dots. Is that fair?

A. It is fair, but this is after --

MR. GALLAGHER: Objection.

A. Sorry. But this is, you know, after, you know, this event came out and they tried to understand, yeah, exactly what would

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happen.

BY MR. SLATER:

Q. And as part of the analysis that ZHP performed in looking back as to why this happened, it was understood that this was not recognized when the process was being created to use zinc chloride due to insufficient study and insufficient research, correct?

MR. GALLAGHER: Objection. Vague, calls for speculation.

BY MR. SLATER:

Q. I'll ask it again. Let me ask a new question, because counsel said that I asked a question that was vague and called for speculation so I want to try to fix it.

ZHP in 2018, in looking back, concluded that the reason this was not figured out and these dots were not connected back in 2011 was because of insufficient research and insufficient study, correct?

MR. GALLAGHER: Objection. Vague.

A. As I already answered, you

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know, previously, you know, the whole industry as well as, you know, the regulator, you know, all, you know, had this knowledge gap, obviously including ZHP.

MR. SLATER: Let's take that document down and go to Exhibit 212, please. If we could, Cheryll, let's go to page -- the Bates number 1308 in the bottom right, the last three digits.

Actually let's stop for a second. Don't go anywhere. I'll just identify the document first.

Q. We have on the screen Exhibit 212, which is a report, and the topic title is "Investigation regarding an unknown impurity," and then in parentheses "Genotoxic Impurity" with regard to valsartan.

Do you see that?

A. Mm-hmm.

Q. Okay.

MR. SLATER: Let's go now to page -- the page that has the 308 as the last three digits, please.

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A. One thing, you know, but just by looking at this document it looks like this is only a draft. We have -- I think have a final, finalized, you know, signed document. So I don't know, should we look at the final document?

Q. No, we'll look at this document.

MR. SLATER: Scroll down a little further, Cheryll, so we get the bottom half of the page, please. Perfect.

Q. Section 5.2 is titled "Control strategy."

Do you see that?

A. Mm-hmm.

Q. Under the heading of 5.2, "Control strategy," it says, "Due to insufficient extent and depth of process research at the early stage, as well as insufficient study and understanding of potential genotoxic impurities, only side reaction product and degradation products were studied, and was unaware of the further

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reaction between degradation products and raw material."

Do you see what I just read?

A. Mm-hmm.

Q. So certainly as of the time this document was drafted, the conclusion at that time was that there was insufficient extent and depth of process research as well as insufficient study and understanding of potential genotoxic impurities. That's what the document states, correct?

MR. GALLAGHER: Object to the questions on this document to the extent the witness said this is not a final version and asked to see the final version.

But, Dr. Li, you should answer, if you can answer.

A. I mean, yeah, based upon this version, you know, this is what it says. But as I said, you know, this statement is still consistent, you know, with the fact, you know, that I already said that, you know, the whole industry as well as, you know, ZHP and

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also the regulators, you know, everybody had the same knowledge gap at the time.

MR. SLATER: Take that document down, please.

BY MR. SLATER:

Q. Who is Charles Wang?

A. Charles Wang, who is a toxicologist, you know, who is the consultant of Huahai or ZHP.

Q. Was he somebody that was an independent consultant, had his own company?

A. Sort of, yeah.

Q. What do you mean "sort of"?

A. He was doing, you know, that -- you know, he is a long-time friend, and so, you know, you know, he is a trained toxicologist, so when we had a -- you know, you know, this issue, you know, when this issue came out we came to him, you know, for help.

Q. I asked you if he had an independent consulting company. Did he have an independent consulting company?

A. That I don't know. I mean, you

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know, whether he set up -- you know, I don't know. I had no details about this.

Q. You said he was a long-time friend. Who was he a long-time friend of?

A. Myself.

Q. How did you know him?

A. We know him because, you know, he and I, we both have been the member of a professional, you know, association, it's called Sino-American Pharmaceutical Association, and he and I, you know, were both, you know, like a member, like long-time members. This is a nonprofit, you know, professional organizations started in New Jersey, I think around time of 1993.

Q. Did you ever work together?

A. No, we never worked together.

Q. And by the way, I think I forgot to ask you the other day, there's someone at ZHP named Eric, and if I don't pronounce his name correctly, let me -- Eric Tsai, T-S-A-I?

A. Eric Tsai, yeah.

Q. Did you work with him in the

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past before you came to ZHP?

A. We actually worked in the same company, but we were not in the same department. Yeah.

Q. What company did you work at with Eric Tsai?

A. Merck & Company. When I first joined Merck & Company in 1998, Eric Tsai, he was already there. Yeah. And I left Merck the first time in 2005, as far as I remember, he still was, you know, with Merck. Yeah.

Q. Was it just a coincidence that the two of you ended up at ZHP, or was there some connection there?

A. Perfectly coincidental.

Q. Coming back to Charles Wang, you said he was a long-time friend. When did you meet him?

MR. GALLAGHER: Adam, are we moving on from the 30(b)(6) to individual?

MR. SLATER: No, we're not.

MR. GALLAGHER: I'm going to object to all this as outside the

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scope of the 30(b)(6).
MR. SLATER: I'm confident that it's within the scope. I'm confident that I'm allowed to ask who he was, because you know who he is, so I don't think you should have an issue with me asking the questions.
MR. GALLAGHER: I don't have a problem with you asking the questions. It's just that it's outside the scope of the 30(b)(6).
MR. SLATER: We disagree.
So I'm going to continue now, okay?
MR. GALLAGHER: Absolutely.
It's outside the scope of the 30(b)(6), but Dr. Li should answer to the extent he knows personally.
BY MR. SLATER:
Q. So I'll ask the question again, Doctor.
A. It's such a long time, you know.
Q. Let me ask the question again.

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I don't mean to interrupt you, but let me just ask the question.
A. Okay. Sure.
Q. How long -- well, rephrase.
When did you meet Charles Wang?
MR. GALLAGHER: Objection. Outside the scope.
A. You know, there's such a long time, so I don't remember exactly which year. I would say somewhere, you know, like -- probably I would say in late, you know, '90s, or maybe early 2000. You know, like late 1990s, somewhere around that period.
BY MR. SLATER:
Q. When you said he was a long-time friend, I might have misheard. I thought maybe that you said "of us," or in plural. So was it with somebody else at ZHP?
MR. GALLAGHER: Objection. Outside the scope.
You can answer.
THE WITNESS: Yeah, sorry.
I don't know, you know, who else, you know, you know, he himself

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considered to be a long-time friend.
I really don't know. I cannot speak for him, okay.
BY MR. SLATER:
Q. Did he know anyone else at ZHP, to your knowledge?
A. Oh, yes.
MR. GALLAGHER: Objection. Outside the scope.
THE WITNESS: Sorry.
BY MR. SLATER:
Q. Who?
MR. GALLAGHER: Objection. Outside the scope.
BY MR. SLATER:
Q. Who else did he know at ZHP, to your knowledge?
MR. GALLAGHER: Objection. Outside the scope.
A. I mean, based upon my personal knowledge, you know, he knows Mr. Jun Du.
BY MR. SLATER:
Q. Do you have any idea how they knew each other?

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MR. GALLAGHER: Objection. Outside the scope.
A. As far as I understand, they probably -- okay, that's just my guess. They probably, you know, essentially, you know, you know, came to know each other.
Also through the same organization, you know, because, you know, this organization, you know, that I just mentioned, it's scientific, you know, you know, oriented. And so every year, you know, this organization will be, you know, you know, holding like conferences, scientific conferences, you know, you know, career, like a workshop, you know, things like that.
And Huahai US, you know, at least for a period of time, you know, was the -- you know, the sponsor of some of the meeting events.
MR. SLATER: Let's put up our next exhibit. We'll call it Number 316. It's CHARLESWANG000289.
(Whereupon, Exhibit Number ZHP-316 was marked for

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identification.)
MR. SLATER: Let's go to the beginning of the e-mail chain on the second page, please.
I want to get the e-mail -- yeah. Can you, Cheryll, possibly scroll up so we can get the -- no, the other way. There you go. Stop. Perfect.
BY MR. SLATER:
Q. Looking now at the second page of this e-mail chain where the Bates number is CHARLESWANG000290.
Do you see that?
A. 000290. Where is the --
Q. It's probably behind the pictures of people.
A. Oh, let me see. Sorry. Okay. Oh, yeah, mm-hmm.
Q. Looking at this e-mail chain, starting with the first e-mail in the chain, which starts at the bottom of the second page, it's an e-mail from yourself, Min Li, to Charles Wang, June 6, 2018.

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And you say you're forwarding -- or subject says "Forward: WHO Report," and you say, "Please see the report."
A. Can I see that? I'm sorry. Can I see that word?
Q. I'm just asking, do you see what I just read, the June 6, 2018 date?
A. Yeah, I see the date, but I don't see any content.
Q. That's the e-mail that we were provided, so I'll ask the next question.
June 6, 2018 is the day after Novartis confirmed to your company that they had identified the NDMA in the valsartan they were testing through the outside lab, Solvias.
We went through that yesterday, right?
A. That was -- as I said, we received the e-mail, you know, you know, they indicated they suspect, you know, that that was the NDMA.
Q. And this is the -- rephrase.

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This is the next day, June 6th, correct?
A. Yes.
Q. You say in this e-mail, "Please see the report." I assume you had spoken with Charles Wang before you sent this e-mail.
Do you recall?
A. I do not recall.
Could I just see, you know, you know, that particular content that you just, you know, reading twice already?
Q. I'm reading literally what's right in front of you, sir.
A. Oh, "Please see the report." Yeah. Yeah.
Q. It looks like you had written to Charles Wang from Yahoo Mail on Android.
Do you see that?
A. Yes, mm-hmm.
Q. What's an Android?
A. What's Android? That was my, you know, US, you know, cell phone, you know, you know, at that time, it looks like.

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Q. Do you know who the manufacturer is of the Android?
A. I don't remember. It could be -- let's see. It could be a Samsung, you know, smartphone, but I really don't remember exactly.
Q. Was that phone turned in to be checked to produce documents to us as part of the production obligations in this litigation?
A. That phone has been dead, I think. Yeah, that phone -- so I think I, you know, changed to my current phone. That phone has been -- yeah.
Q. That phone is dead?
A. Yeah.
Q. Is it buried? Is it buried, or is it still available?
A. No, it's no longer available. It has been disposed, you know, because it's no longer usable, totally unusable.
Q. We know it was working on June 6, because we see the e-mail that you sent from your Android, right?

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A. Yes.
Q. June 6, 2018 it was working, right?
A. Oh, yeah, uh-huh.
Q. When did it stop working?
A. When did it stop working. Sometime after -- I don't -- see, I don't remember exactly. It -- let me see. I just don't remember, you know, you know, all of these details.
Q. Did that phone die in 2018 or 2019?
A. I just --
MR. GALLAGHER: Objection.
THE WITNESS: Sorry, go ahead.
MR. GALLAGHER: Objection. Asked and answered.
You can answer, Dr. Li.
A. Yeah. I just don't remember right now. I mean...
BY MR. SLATER:
Q. Did you pay for that phone, or did your company pay for it?
A. I paid for that phone myself.

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Q. When you replaced that phone, did you do that yourself, or did the company have any part of you replacing the phone?
A. Everything, you know, I did myself, like I paid for myself.
Q. The phone that you replaced this Android with is what, what type of phone?
A. It should be, you know, this new Samsung phone that I'm using right now.
Q. Do you know what type of phone it is?
A. What type of this phone. At the time that I bought it should be kind of like a top of the line, you know, you know, Samsung phone, but I don't remember exactly, you know, the model.
Q. Is it in the room with you right now?
A. Yeah, it is in this room, yeah. I can take a look if you want.
Q. Can you take a look right now and tell me what kind of phone it is?
A. Sure.

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Oh, let me see, it's probably from the setting, right, looking about the phone. Okay. It's model number SM-N950U.
Q. Is it an Android, is it a model -- is that the model?
A. Yeah, it should be Android operating, yeah. Everybody else, yeah, I think other than -- other than the, like, Apple, right.
Q. When you bought this new phone, did you get some sort of a warranty or some sort of protection plan where if something happened to it you could use that to help fix it?
A. No.
MR. GALLAGHER: I'm going to object to this line as outside the scope as well.
But please go ahead.
A. Yeah, I think we usually don't buy those protection plans.
BY MR. SLATER:
Q. What would you need to do to tell me the day that you got the new phone so we'd know when you replaced the old phone?
MR. GALLAGHER: Objection. Asked and answered.
A. I really need to, you know, dig into some of the detail if I, you know, if I, you know, you know, have to tell you exactly the -- I need to -- I need to do some research.
BY MR. SLATER:
Q. Sometimes the Samsung phones have the name on the back of the phone. Can you look at the back of your phone and see what type you have now?
A. The name of the phone. On the back cover of my phone? Let me see. I need to remove the protection. Hold. Galaxy Note 8, yeah.
Q. You said Galaxy Note 8?
A. Yes.
Q. Was your Galaxy Note 8 phone provided to your company for documents and information to be provided to us as part of this litigation?
A. No. Because, you know, once I

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got this Galaxy phone, you know, it's -- I don't think it's been used with this communication.

Q. Where did you get the phone? Did you buy it at a store?

A. Yeah, I buy it in the store, yes.

Q. What store did you buy it at?

MR. GALLAGHER: I'm going to object to this entire line as outside the scope and, you know, bearing into --

MR. SLATER: Well, I'll ask you a question, Counsel, maybe it will move things along.

Can you represent right now that Dr. Li's phones were both properly collected and reviewed to make productions of documents and information to us pursuant to the discovery obligations in this litigation?

MR. GALLAGHER: I can represent that we collected from all the devices

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that we needed to collect from to get the documents to meet our discovery obligations.

MR. SLATER: Does that include the phone he was using on -- rephrase.

Does that include the phone that was being used on June 6, 2018?

MR. GALLAGHER: I think he told you that phone is -- no longer exists.

MR. SLATER: Well, I'm asking you because we're asking these questions so we can match up the dates and find out when the phone "died" and we're going to track that phone.

MR. GALLAGHER: If you want to -- if you want to continue, I'm just objecting as outside the scope and, you know, veering in wildly irrelevant.

If you want to, you know, submit a request in writing for us to look at something, we're happy to do that. But you're welcome to do your deposition as you'd like. I'm just

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objecting outside the cope and veering into wildly irrelevant.

BY MR. SLATER:

Q. While we're on it, I had asked you on the first night of the deposition when you were first told about the deposition, and you said it was by an e-mail about six months ago, and I asked if you would check that date. Did you do so?

A. I'm sorry, check what?

Q. The date of the e-mail that you received the first time you were told you were going to be deposed in this litigation.

MR. GALLAGHER: Object as calling for speculation, and to the extent it calls for attorney/client privileged information.

And to the extent you know and can answer without disclosing information regarding communications with your attorneys, you can. But to the extent it would disclose information communicated from attorneys for ZHP, I instruct you not

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to answer.

A. So -- so I -- you know, well, first of all, I haven't had a chance, you know, you know, you know, to do that. But I guess after, you know, after this deposition, you know, I can take some effort, you know, to look it up.

But, you know, these past few days, you know, I have been very exhausted, and I also need to, you know, read through some of the, you know, documentation, you know, right, to -- for continuous prepare, you know, for this deposition, so I really haven't done, you know, this information search.

BY MR. SLATER:

Q. You told me on -- rephrase.

You told me that it would have been an e-mail from Maggie Kong, so you could just search your e-mails for her name and see --

A. No, I said that --

MR. GALLAGHER: Let me -- slow down. Sorry.

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Again, I'm going to object to the extent you're asking him to speculate, and to the extent it calls for attorney/client privileged information.

Adam, if you want to send us a request we can -- in writing, we can go back and look, and to the extent that it doesn't involve attorney/client information we can share that.

A. I think, yeah, I think, I think my counsel will provide an accurate, you know, dates, yeah.

BY MR. SLATER:

Q. We also talked the other day about when your Lenovo ThinkPad broke and you replaced it. Did you look into what the date was when that happened?

A. That --

MR. GALLAGHER: Same objection.

BY MR. SLATER:

Q. Lenovo ThinkPad, I'm sorry.

A. That, as I said, that probably,

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let's see, I think it's -- it's probably somewhere around May 2018.

But again, you know, you know, I need to go back, you know, to talk to, you know, my IT people, you know, to see what exactly date, you know, they provided, you know, this current one, you know, to me.

MR. GALLAGHER: And, again, Adam, same objections. And if you want to send us a request in writing, we can take that under advisement.

BY MR. SLATER:

Q. Why did you contact Charles Wang -- well, rephrase. Let me ask you this.

Did you contact Charles Wang as a result of Novartis notifying your company of the identification of NDMA on June 5, 2018? Is that why you contacted him?

MR. GALLAGHER: Objection. Vague, and lacks foundation.

A. The reason -- first of all, obviously, you know, because we received a notice and we, you know, need to have an expertise, you know, to evaluate from the,

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you know, toxicological perspective.

And also, as I said, because he is a long-time friend of mine, and I know he is a toxicologist, so that's how, you know, I naturally, you know, thought of him and turned to him for help.

BY MR. SLATER:

Q. Did you see him as an expert in toxicology?

A. Oh, yeah, yeah.

Q. Did you consider him somebody who would provide you reliable information?

A. Yes.

Q. Was he somebody that you trusted?

A. Oh, yes.

MR. SLATER: Let's scroll up, Cheryll, to the next e-mail in the chain on the second page. Perfect.

Q. Now, looking at the June 10, 2018 e-mail sent at 11:49 a.m. from Charles Wang to yourself, do you see that?

A. Mm-hmm.

Q. I have another question.

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Rephrase.

Why is it that you and Charles Wang were communicating on your Yahoo accounts rather than on business accounts?

A. I think the main reason is, you know, he is a long-time friend of mine, and, you know, we've been using, you know, Yahoo e-mail or personal e-mail, you know, for quite long.

So during that time, you know, because this events was so urgent, right, so I, you know, did it, you know, just naturally, you know.

And because, you know, his Yahoo e-mail is also like sort of like stored on my, you know, Yahoo, right? So once I type, you know, like "Charles," that e-mail naturally will appear.

So, yeah, it's urgent, it's for convenient. Yeah, that's how it happened.

Q. Did you or anybody else from ZHP, to your knowledge, contact any other toxicologists or experts regarding the health or safety issues with NDMA in June 2018?

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A. I don't recall. I mean, for me I only contacted the Charles Wang. But anyone else, you know, from ZHP contact anybody else, I just don't know.
Q. Was Charles Wang the only outside toxicologist your company consulted in connection with the NDMA in the valsartan?
A. I cannot -- you know, I do not have this knowledge like somebody else did.
Q. Is there any other toxicologist other than Charles Wang that anybody at ZHP consulted with or spoke to regarding the NDMA in valsartan?
MR. GALLAGHER: Objection. Vague.
A. You know, as I said, you know, from my perspective, I only contact or consulted with Charles Wang.
BY MR. SLATER:
Q. As part of your preparation to testify for your company, did you ask others if they had contacted any other toxicologists?
A. I haven't asked.

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Q. Looking now at the June 10, 2018 e-mail, Charles Wang wrote to you and said, "Hi Min, The attached is draft report for NDMA."
A. Mm-hmm.
Q. "I can take out the limit of 0.011 parts per million if you are unable to achieve it."
Do you see that?
A. Mm-hmm.
Q. So in this report that he wrote, he put in a maximum acceptable limit of 0.011 parts per million for on a going-forward basis, correct?
A. Yes.
Q. And he asked you if you -- he -- rephrase.
And he's asking you here, do you want me to change it if ZHP can't get to that level; that's what he's asking you, correct?
A. Mm-hmm, yes.
Q. Is that what a good scientist does in providing scientific advice, provide

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their opinion and their advice, but then say, well, I'll change it if for commercial purposes you need me to?
MR. GALLAGHER: Objection. Vague.
A. I think your statement is twisted, you know, the fact. Okay.
At that time, okay, nobody had any idea like what limit should be set, okay. So very naturally there would be a discussion, what would be a reasonable, you know, you know, limit to set, okay.
So I think that, you know, based upon the context, you know, everything is written here, it looks like, you know, the 0.011 ppm was a number, if I remember correctly, you know, proposed by a Novartis, you know, toxicologist, okay.
And that person, you know, you know, derived this number from, I think, an animal study. It's not based upon rodent, okay. I think it's based upon, you know, a primate, maybe monkey or something.
So that, you know, from that

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PD50, you know, that person derived a limit of 0.011 ppm. Okay.
So later, you know, I think if you look at the European regulatory, you know, you know, document, you know, they spent, you know, quite a -- you know, you know, quite a few, like maybe one page or whatever, discussing what the value should be used.
So I think the conclusion or the eventual consensus is that for those, you know, animal carcinogenic study, it would have been more reliable to use, you know, you know, data from rodent.
The very reason was because primate -- you know, the lifespan of primate, you know, is too long, right? You know, so you would have -- you know, quite a lot of other factors would impact, you know, how a tumor would be produced.
So I think, you know, if you ask somebody, you know, you know, who are familiar or some, you know, like a toxicologist who are familiar, you know, with

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these issues, you know, or everything that I, you know, you know, you know, are talking about here, you know, people would agree, you know.

So that's how the 0.3 ppm, right? It's from a rodent, you know, study. Okay.

So yeah, at the very beginning, you know, as I said, even FDA or European regulatory agency, you know, you know, didn't know, you know, how to set, and -- yeah, so it's very -- you know, everything, you know, was progressing, and actually is still, you know, progressing.

BY MR. SLATER:

Q. Reading along in the e-mail, Charles Wang said, "I can take out the limit of 0.011 ppm if you are unable to achieve it. See if your client accept the limit recommended based on the maximum intake of NDMA via food or exposure of indoor air. The limit of 0.011 ppm is calculated based on the EPA recommended limit for underground water, which won't cause the risk to exceeding the

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tumorigenesis rate of 10e-6 in lifespan of human being. Let me know if you any comments or questions."

That's what he wrote to you, right?

A. Okay. Oh, yeah. So -- yeah, okay. So based upon -- I'm sorry. Yeah, based upon, you know, you know, this whole e-mail, yes.

So I take it back, you know, you know, referring the 0.011 ppm, you know.

But between Novartis and the ZHP, we did have that communications, you know, in terms of what limit, you know, you know, should be set.

So, as I said, the data from, you know, you know, you know, from that primate, it would be lower than 0.3.

So, I mean, this 0.011 could be from, you know, the primate, okay, because they are -- you know, both are lower than the 0.3.

But, you know, in the end, as I said, you know, after, you know, all of the,

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you know, you know, discussion progressing, so now regulatory agencies, particularly like, you know, FDA, right, now is setting a limit of 0.3, which is based upon, you know, the rodent carcinogenic study.

MR. SLATER: Cheryll, if you could scroll up to the next page so we can get to the beginning of the next e-mail, which starts on the next page, please. Perfect.

Q. Later that day now on June 10, 2018 at 9:09 p.m., where the prior e-mail had been at 11:49 a.m., Charles Wang writes to you again.

Do you see that?

A. Mm-hmm.

Q. He writes to you to provide you a statement in the ICH M7 guideline.

Do you see that?

A. Yeah, "TTC-based Acceptable Intakes." Okay. Mm-hmm.

Q. And it has some threshold of toxicological concern-based acceptable intakes, and it has some information on that.

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Do you see that?

A. Yeah, let me read through. TTC-based...

(Witness reviewing document.)

THE WITNESS: So that's the first paragraph, 7.2, "Based on Compound Specific Risk Assessment."

Okay. "Mutagenic Impurities with Positive Carcinogenicity Data (Class 1 in Table 1). Compound-specific risk assessments to derive acceptable intakes should be applied instead of the TTC-based acceptable intake where sufficient carcinogenicity data exist. For a known mutagenic carcinogen, a compound-specific acceptable intake can be calculated" -- "and linear extrapolation as a default" -- okay. Yeah.

MR. GALLAGHER: Doctor, when you read out loud, the court reporter has to take everything down that you're saying. So just when you're

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reviewing the document, for ease of everyone, the document says what it says.

THE WITNESS: Okay. I'm sorry. Yeah.

Yeah, I finished reading, yes.

MR. SLATER: Counsel, I would appreciate it if you would not instruct your witness not to say things out loud.

MR. GALLAGHER: I'm not instructing him not to say things. I think he didn't realize.

THE WITNESS: Well, yeah, I just read through the e-mail.

MR. GALLAGHER: If you feel it's necessary for you to read it out loud, you should read it out loud. I'm not sure if that's what you were intending to do, so...

Please proceed.

THE WITNESS: Okay.

BY MR. SLATER:

Q. You can see that after --

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rephrase.

You can see that in this e-mail Charles Wang says. "Hi Min, See statement in ICH M7 regarding" -- and then you see that's what it says, right?

A. Mm-hmm.

Q. And then he has some information about acceptable intake levels and it depends on what class somebody is placed in.

Do you see that?

A. Yes.

MR. SLATER: Cheryll, if you could scroll down to the top half of the following page, we'll go to the carryover, and there's a table.

Q. And you remember, that table is in the ICH M7 guideline, correct?

A. Yes.

Q. And we see it says Table 1 --

MR. SLATER: Scroll up a millimeter more so we can get the bottom of the e-mail, please. Just a little -- that's it. Perfect.

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Q. We see the table, and then you can see underneath that it says, "NDMA should be Class 1 compound" giving its" -- "given its well known mutagenicity nature of this compound. Charles."

Do you see that?

A. Yes.

Q. So he's saying that it should fall into Class 1 under the ICH guidelines, which is defined as a known mutagenic carcinogen, correct?

MR. GALLAGHER: Objection. Vague, and calls for speculation.

A. It's a known mutagenic carcinogenic to animal.

BY MR. SLATER:

Q. A Class 1 impurity is defined on this table as a known mutagenic carcinogen, and he's saying NDMA should fall into that class, correct?

MR. GALLAGHER: Objection. Vague, calls for speculation, and to the extent it calls for expert testimony.

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A. That's what he said.

But I should emphasize, in this particular case NDMA is a known mutagenic carcinogen to animal.

BY MR. SLATER:

Q. Let's go up now to the beginning of the e-mail. Rephrase.

Let's go to the beginning of the whole -- rephrase.

Let's go to the top now, to the last e-mail in the chain, please.

MR. SLATER: Thank you, Cheryll.

Q. Looking now at the next e-mail in the chain, June 12, 2018, Charles Wang wrote to you at 3:18, it looks like.

Do you see that?

A. Yes.

Q. And he says -- rephrase.

In this e-mail Charles Wang says, "Hi Min, Looks like IARC does consider NDMA as a Class 2A agent. However, according to the definition of Class 2 in ICH M7(R1) guideline, the Class 2 compound should be a

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"Known mutagens with unknown carcinogenic potential (bacterial mutagenicity positive*, no rodent carcinogenicity data)."

Do you see that?

A. Yes.

Q. And he actually highlighted the "no rodent carcinogenicity data."

Do you see that?

A. Let's see. No rodent -- yeah, highlighted, yes.

Q. The e-mail continues, "There are plenty rodent carcinogenicity data for NDMA (see revised report in the attached, page 4). In Fisher MSDS, NDMA has been classified as Class 1B for carcinogenicity (attached)."

Do you see that?

A. Yes.

Q. He then says, "Guess you can argue with your client and see if they accept IARC's classification and agree to control the level at threshold of toxicological concern (1.5" -- is that micrograms or milligrams per day?

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A. Microgram.

Q. And we went over yesterday, and I can pull it out if we need to, that the ICH M7 guideline actually said that's inapplicable to those compounds that are considered to be in the cohort of concern like nitrosamine compounds. Remember we went through that yesterday?

MR. GALLAGHER: Objection to the extent it mischaracterizes his testimony.

A. Yes, we did went through.

MR. SLATER: In fact, Cheryll, let's pull up now as Exhibit 317 the material safety data sheet referred to here by Charles Wang.

(Whereupon, Exhibit Number ZHP-317 was marked for identification.)

BY MR. SLATER:

Q. You know what a material safety data sheet is, correct?

A. Yes.

Q. What is a material safety data sheet?

A. Well, based upon my understanding, it is a document that typically utilized in the storage and transportation of a chemical.

Q. It also provides hazard and risk information about the chemical, correct?

A. Right. Being one of the section or two, you know, some of the sections, they talk about -- yeah, that's why, you know, just to help people, you know, to be properly handling, you know, the chemical during the transportation or storage.

Q. Looking now at the Classification section, under "Carcinogenicity" it says "Category 1B," correct?

A. I'm sorry, where?

MR. SLATER: You've got to scroll up, Cheryll, just to get that box that has the categories in it. Perfect. That's good. Yeah. I don't want to go to the next page. No, I

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don't want to go to the next page.

Q. Looking at the classification category, I'm just looking to identify what Charles Wang was referring to, he said that it refers to NDMA as a Class 1B.

Do you see that?

A. Mm-hmm. Yes.

MR. GALLAGHER: Objection.

MR. SLATER: Okay. We can take that down.

A. But I don't know how, you know, this MS --

MR. SLATER: Cheryll, you can take that down. We're going to the next document.

MR. GALLAGHER: You can complete your answer. And if you need to see the document, we can --

BY MR. SLATER:

Q. I'll put it back up. I --

A. You know, I --

Q. If you want to see the document again, I'll go through the whole thing --

A. That's fine. But I just need

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to point out, you know, it looks to me, you know, I don't know -- first of all, I don't know what this Class 1B, you know, in this particular MSDS, you know, they are referring to.

Okay. If they are referring to the same, you know, you know, IARC categorization, you know, then it is just not correct, because if they look at the, you know, IARC classification, you know, even as of today, you know, NDMA is classified as 2A, okay.

Q. We literally just went through in Exhibit 316 where Charles Wang, who you told us earlier is an expert, someone who is reliable and who you trust, told you that he disagrees with the Class 2A classification. That is what the e-mail said.

Is that a correct statement that I just made? Yes or no.

A. He --

MR. GALLAGHER: Objection. Calls for speculation, to the extent it mischaracterizes the document and

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the testimony.

A. You know, you know, from the e-mail he just referring to this MSDS, okay. He didn't, you know, you know, you know, go further commenting, you know, on how this Class 1B, you know, was assigned or whether it's -- it may be misleading or this may be incorrect. You know, this is just a -- you know, based upon everything, you know, that I know.

MR. SLATER: Okay. Cheryll, I'm going to skip ahead two exhibits in our list to CHARLESWANG000430, please, and we'll make that Exhibit 318.

(Whereupon, Exhibit Number ZHP-318 was marked for identification.)

BY MR. SLATER:

Q. On the screen is Exhibit 318, a June 22, 2018 e-mail from Charles Wang to yourself, correct?

A. Yes.

Q. Now, in this e-mail he's still

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on his Yahoo account, but you're on your work account. Do you know why that is?

A. You know, again, I don't remember exactly, you know, you know, you know, you know, that I talked to him or whatever. So I would say a reasonable explanation is, you know, as I explained, you know, right, you know, in the -- during the very early phase, you know, it was quite urgent so I just sent him through my personal e-mail, right.

And but then, you know, a few days or, you know, after this event, you know, I probably communicated or talked with him, you know, over the phone or whatever, you know, just I -- I just told him, you know, probably, you know, he should utilize my company e-mail.

Q. Looking now at this e-mail, Exhibit 318, Charles Wang writes to you, and in the first paragraph he's providing you some information about some -- a paper and some sort of a reply to a paper.

Do you see that?

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A. I'm sorry, what?

Q. Rephrase. Withdraw it.

MR. SLATER: Could you scroll up, please, Cheryll, a little more so we can capture the -- that's it. Perfect.

Q. Looking now at the June 22, 2018 e-mail, which we've marked as Exhibit 318, to you, and I want to look, if we could, at the second paragraph of that e-mail, okay?

A. Mm-hmm.

Q. Charles Wang says, "Hi Min," and then in the second paragraph says, "I suggest Huahai to hire a carcinogenicity expert consultant to perform the analysis, who knows risk assessment of carcinogen and kept updated in regulatory guideline and standards in this field. If needed, I can recommend a couple to you for consideration.

"Best, Charles."

Do you see that?

A. Yes.

Q. So he's basically telling you,

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I think we need to get somebody in who is a real high-level expert in this field to help us out with this project, and he's willing to reach out to people he knows to try to get you such an expert, correct?

MR. GALLAGHER: Objection. Mischaracterizes the document.

A. Yeah, he said he can recommend a couple, yes.

MR. SLATER: Let's take that down now. And we're going to go to Exhibit 319, which is going to be CHARLESWANG000447.

(Whereupon, Exhibit Number ZHP-319 was marked for identification.)

MR. SLATER: If we could, let's go to the first e-mail in the chain, which starts at the very bottom of the second page, please. Perfect.

BY MR. SLATER:

Q. The first e-mail in the chain starting at the bottom of the second page is dated July 5, 2018 at 1:50 p.m.

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Do you see that?

A. Mm-hmm. Yep.

Q. The e-mail reads, "Hi Jim, Long time no see. Hope everything is going well."

MR. SLATER: Let's scroll down to see the rest of the e-mail.

Q. "Friend of mine is looking forward a consultant in United States to help them define their product at FDA. Give me a call if you are interested. My cell number is" -- and then the cell number is redacted.

Do you see that?

A. Yes.

Q. Then he says -- rephrase.

Then Charles Wang says, "For your information, I have moved back to US and still working for GSK" -- that would be GlaxoSmithKline, correct?

A. Yeah, looks like, uh-huh.

Q. -- "still working for GlaxoSmithKline in their safety assessment group in Upper Merion, Pennsylvania. Hope to meet you again sometimes for catch up.

"Talk to you later and enjoy your summer.

"Best regards, Charles."

Do you see that?

A. Mm-hmm.

Q. And are you aware that, in fact, Charles Wang at that time was the director of safety assessment for GlaxoSmithKline?

A. I don't know -- I don't remember his title, but, yeah, it looks -- yeah, he was working, yeah, for GSK.

Q. Did GSK know that in June and July of 2018 Charles Wang was consulting for ZHP regarding the NDMA contamination in valsartan?

MR. GALLAGHER: Objection. Vague, and calls for speculation.

A. I have no knowledge of that.

BY MR. SLATER:

Q. Did Charles Wang ever say to you anything to the effect of, I'll do this for you, but we can't tell my employer, or we can't let my employer know that I'm consulting on the side for another

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pharmaceutical company?

MR. GALLAGHER: Objection. Argumentative, and foundation.

A. I don't think this kind of conversation ever occurred.

BY MR. SLATER:

Q. Why did you consult with Charles Wang, who was employed another company, rather than hiring an independent toxicological consultant?

MR. GALLAGHER: Objection. Lacks foundation.

A. As I told you, he has been a long-time friend of mine, okay, and we didn't know anybody, you know, else in terms of the, you know, professional toxicologist, right? And due to the urgency, you know, you know, of this nature, we had to, you know, invoke him, right?

I don't know if you understand, you know, the procedure if you want to hire somebody, right, from a company. Like, you know, there's a lot of red tape you have to go through.

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So due to the very urgent nature, you know, we tried to solve this problem as soon as possible. So I naturally, you know, you know, think of him and, you know, just contact him.
BY MR. SLATER:
Q. When you say "there's a lot of red tape," red tape at ZHP to hire a professional consultant who is independent?
MR. GALLAGHER: Objection. Foundation.
Go ahead.
A. From a company perspective, no matter, you know, who you hire, okay, you have to go through certain procedures, right? Like, you know, a contract for service, you know, like a confidential, you know, agreement, whatever. You know, this will take at least a few days.
But here, you know, because the urgency, you know, of the nature, right, we don't want to waste any single day.
BY MR. SLATER:
Q. So you didn't pay Charles Wang

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for any of the consulting he did for ZHP?
A. That I have no idea.
Q. You don't know if Charles Wang was paid for the work he did for ZHP?
A. I have no knowledge of that, okay, because this is -- you know, this has been outside of my -- you know, yeah, because I'm -- as I said, I'm a technical person. I just reach out to him, you know, you know, for his help.
Q. Did you ever discuss with Charles Wang the subject of him being compensated for consulting for ZHP while he was employed by GlaxoSmithKline as their director of safety assessment?
MR. GALLAGHER: Objection. Lacks foundation.
A. As I said, you know, for this matter I don't know. I have no idea.
BY MR. SLATER:
Q. You have no idea if you ever -- well, let me ask the question. I want to make sure I'm clear.
Did you ever ask any --

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rephrase.
Did anybody ever tell you that Charles Wang was paid anything for consulting for ZHP with regard to the NDMA contamination of ZHP's valsartan?
A. I don't remember.
MR. GALLAGHER: Objection. Foundation.
BY MR. SLATER:
Q. That would be pretty easy to find out, right? If we requested that from you, your company should have a record if they paid him, right?
MR. GALLAGHER: Objection. Lacks foundation.
A. You can -- I would say you can make, you know, a request, right, just like Patrick said. You can make a request, you know, through all counsel. They can find out for you.
BY MR. SLATER:
Q. Would Jun Du know if Charles Wang was paid for the work he did for ZHP?
MR. GALLAGHER: Objection.

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Calls for speculation.
A. You can ask him, okay?
BY MR. SLATER:
Q. Did you ever speak to the chairman of your company, Mr. Chen, regarding any of your interactions with Charles Wang and what he was telling you?
A. No.
Q. Did you ever speak to Baohua Chen at all about the nitrosamine contamination of valsartan sold by ZHP? Did you ever discuss that with him?
A. We discussed the matter, you know, in meetings.
Q. Meetings in person?
A. No, not in person.
Q. How were those meetings held?
A. I mean, like, you know, when this event basically occurred, you know, you know, it become the top priority of the company.
So as the CEO of the company, you know, you know, he organized, you know, quite a few meetings, basically just to

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ensure, you know, the investigation being conducted, you know, as soon as possible, and, you know, basically just ask us, you know, what kind of resources that we need, basically.

Q. Were those meetings that you talked about held in person? Well, rephrase.

You said the meetings were not held in person. So how were they held?

A. You know, with a group, like, you know, with a group of peoples.

Q. Was it over the telephone? Was it by videoconference? How did you communicate with one another in those meetings?

A. Sir, as I said, there are different meetings, okay? Some meetings, I don't -- you know, I don't remember, you know, you know, all the details. But some meetings, you know, all the participants, you know, were attending in person, some meetings probably, you know, involving some telecommunications.

Q. So you did have meetings in

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person with Mr. Chen about the nitrosamine contamination of the valsartan?

A. Well, in person, okay, I thought you mean like, like, just, you know, like one-on-one meeting, you know. But, yeah, like a -- when -- a group of meeting, yeah, both Mr. Chen and I as well as other members of the management, yeah. Yeah, at least, you know, yeah, we were attending some of the meeting, you know, when both Mr. Chen and myself were physically, you know, attending the meetings.

Q. So you said meetings took place in person, right?

A. Some meeting, yeah, some meeting, yeah, were attended in person, yes.

Q. Were some of the meetings by videoconference?

A. Yeah, uh-huh. Not videoconference. I don't think you -- you know, you -- we don't have videoconference, usually just teleconference.

Q. You said usually teleconference. Did at least one of the

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meetings involving Mr. Chen regarding the nitrosamine contamination of the valsartan take place over videoconference?

A. I don't remember that ever happened.

MR. GALLAGHER: Adam, we've -- you can finish -- we've been going about an hour and 20 minutes. When you get to a natural --

BY MR. SLATER:

Q. Did any of the meetings take place by telephone?

A. As I said, some of the meeting may, you know, may be held, you know, with some attendants, okay, joining by teleconference.

Q. Teleconference means by telephone?

A. Yeah, by telephone, yes.

Q. Did you attend every meeting that Mr. Chen organized and attended regarding the nitrosamine contamination of ZHP's valsartan?

A. I don't think so, like did I

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attended every meeting, because there's a different, you know, you know, you know, aspects dealing with this issue, right.

And, for example, the issue regarding like recall, you know, because I -- you know, as I said, I'm a technical person, those meetings, you know, I never attended, you know, those kind of meetings because it's outside of my scope, outside of my responsibility.

Q. You said --

A. Yeah.

Q. You said that Mr. Chen organized meetings because he was the CEO. So you don't know how many meetings took place or who attended all those meetings?

MR. GALLAGHER: Objection. Calls for speculation.

Go ahead.

A. As I said, you know, I -- those information I'm not, you know, within my responsibility, okay.

BY MR. SLATER:

Q. Well, I'm not asking for your

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responsibility. I'm asking if you know how many meetings took place and who attended each of them.
A. I don't --
MR. GALLAGHER: Objection. Calls for speculation.
A. I don't remember.
BY MR. SLATER:
Q. How many meetings did you attend with Mr. Chen regarding the nitrosamine contamination of ZHP's valsartan?
A. Again, I don't have accurate numbers.
Q. Was it 10 meetings, was it 20 meetings? Can you estimate, please?
A. I just cannot.
Q. You have no idea how many meetings you attended with Mr. Chen?
A. I don't keep, you know, you know, you know, those things.
Q. I'm just asking if you can recall how many meetings. You said this was top priority of the company at the time. I would think you could recall roughly how many

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meetings you attended with the chairman of the company about this crisis.
MR. GALLAGHER: Objection. Argumentative, and asked and answered.
BY MR. SLATER:
Q. Can you recall?
A. No, I cannot recall the accurate number.
Q. Can you give me an estimate?
MR. GALLAGHER: Objection. Asked and answered.
A. As I said, you know, I don't want to provide -- you know, you know, because I don't have this memory, so I don't want to, you know, provide any specific number, okay?
BY MR. SLATER:
Q. Well, can you tell me your best estimate, please, or are you unwilling to do so?
MR. GALLAGHER: Objection. Argumentative, and asked and answered.
A. So if you want to say, you know, the best estimate by now, you know, you

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know, at this time I would say probably, you know, maybe single digit or maybe up single digit.
BY MR. SLATER:
Q. What does that mean, "single digit or maybe up single digit"?
A. Like, you know, anywhere like maybe between five or nine or something like that.
Q. Do you recall what was discussed in those meetings?
A. As I said, I don't, you know, recall all the exact, you know, you know, you know, contents. Basically, you know, you know, the instruction was, you know, we need to, you know, put all the efforts -- you know, the company will support utilizing all the resources, you know, to push this forward as soon as possible.
Q. Using all the resources -- I'm sorry.
When you say using all the resources, did that include making sure that there wouldn't be any "red tape" like you

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said before if you needed to hire an expert consultant to advise the company, for example, on toxicology?
MR. GALLAGHER: Objection. Lack of foundation.
A. This topic was not discussed, okay. So in terms of the resources, from my perspective, okay, it was, you know, you know, we need to -- we need to purchase additional, you know, high-end instrument, okay, particularly like a mass spectrometry, a GC-MS, GC-MS/MS, you know, stuff like that. So he indicated he will give the full support, like, you know, as long as, you know, yeah, like how many, whatever, you know, whenever that I, you know, propose he will, you know, approve the purchase of these instrument.
BY MR. SLATER:
Q. Were notes or minutes taken of these meetings with Mr. Chen?
A. I don't remember.
Q. Did you take notes of these meetings?

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A. No.
Q. Did you see anybody else taking notes during these meetings?
A. I didn't pay attention to that.
Q. So you would go to meetings with the chairman of the company about a situation that was the top priority of the company, and you wouldn't take any notes during those meetings at all?
MR. GALLAGHER: Objection. Argumentative.
And we're getting close to -- towards an hour and a half, if you get close to a breaking point.
A. I didn't take note.
BY MR. SLATER:
Q. Is that your typical practice, you go to important meetings and you take no notes at all?
MR. GALLAGHER: Objection. Vague, and argumentative.
A. Because those meetings, you know, you know, from my perspective, as I said, you know, it's very specific, okay.

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Because for me, I just need to have the funding to purchase these instrument, so, you know, for these simple things I don't think it's necessary, you know, for me to take note. You know, he just, yes, you know, then go ahead.
BY MR. SLATER:
Q. Are you saying that you had five to nine meetings, which is your estimate, and at every one you discussed buying equipment to do testing, and that was the whole meeting every time? You're not saying that, are you?
A. No, I'm not saying that.
MR. GALLAGHER: Objection.
BY MR. SLATER:
Q. Do you remember what else was discussed in those meetings with Mr. Chen, the chairman of the company?
A. Look, you know, as I said, I don't remember, you know, exactly, you know, you know, all the other things, okay.
The most obvious things is, or the most clear thing is that Mr. Chen was

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fully support, okay, in terms of, you know, allocating funding, you know, for the instrument, you know, that I need.
The other meeting, it's most likely he was asking, you know, for our progress, for example, how the method development was ongoing, you know, stuff like that.
Q. Okay. Did Mr. Chen say any -- well, rephrase.
Did Mr. Chen ever tell you or the people in your meetings -- rephrase.
During the meetings you attended with Mr. Chen, did he take notes? Did you ever see him taking notes?
A. No.
Q. Did anybody take notes in these meetings that you ever observed?
A. I just pay attention mostly to Mr. Chen when I spoke, you know, to him.
Q. When you were in these meetings, did you ever notice anybody in the meetings taking notes?
A. I don't re --

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MR. GALLAGHER: Objection.
Go ahead.
A. I don't recall, okay?
BY MR. SLATER:
Q. So a roomful of people meeting with the chairman of the company about a situation that's the top priority of the company multiple times, in all those meetings you never took notes, Mr. Chen never took notes, and you never saw anyone else take notes.
That's your best recollection, is that what you're testifying?
MR. GALLAGHER: Objection. Argumentative, asked and answered, vague, and compound.
A. That's not what exactly what I told you. Okay. What I can tell you is Mr. Chen, he didn't take notes, okay? And I didn't take note. Who else, I don't remember, okay?
BY MR. SLATER:
Q. Were there ever agendas circulated for these meetings; for example,

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by e-mail?
A. I don't know. I don't remember.
Q. When these meetings were scheduled, were e-mails sent out or any sort of calendar sent out so everybody would know the date and time and place of the meetings?
A. I don't remember. I mean, but one thing is, you know, usually, okay, I can tell you my -- you know, like for Mr. -- you know, for meetings with Mr. Chen, usually, you know, his, you know, secretary, you know, would make phone calls.
And one of the reason probably was he was quite busy, so we just -- you know, a lot of times we just stand by. And so once he had time, his secretary would call, call us, you know, to go to meeting rooms, you know, with him.
Q. Who was his secretary? What's her name?
A. There is a --
Q. Who is Mr. Chen's secretary?
A. There are a group, you know, of

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people, okay. I don't know exactly, you know, who would be designated.
I think the best, you know, answer, if you can, you know, maybe you can also go through my counsel, you know, making a formal request, they can provide it, you know, from the staff of Mr. Chen. You know, they probably can give you, you know, a much more accurate, you know, because I don't want to, you know, you know, guess.
Q. You know who works for Mr. Chen. Tell us the names of the people that work for him as his secretaries and assistants.
MR. GALLAGHER: Objection. Asked and answered.
And, Adam, we've been going over an hour and a half now.
MR. SLATER: I'm in the middle of a line of questioning. I don't want to break this deposition now. I don't think it would be appropriate.
MR. GALLAGHER: I'm not sure where you're going, but okay.

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A. His chief of staff, okay, is Ms. Maggie Kong, as I mentioned the other day.
BY MR. SLATER:
Q. Is she the person who would call you to tell you meetings were being scheduled?
A. Sometimes she called me; sometimes, you know, her staff.
Q. Who are the staff members that worked for her who would contact you?
A. You know, there would be different, you know, people, okay, so I don't remember, you know, you know, very specifically for, you know, exactly, you know, who under her, you know, called me, okay?
Q. Can you remember anybody else's name that contacted you, other than Maggie Kong?
A. I mean, you know, this is for so long, so I couldn't, you know, give you an accurate. You know, I don't want to provide, you know, you know, you know, anything, you

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know, inaccurate, okay.
So only thing for sure, you know, yeah, it would be somebody -- you know, yeah, sometimes could be her; sometimes, you know, could be someone, you know, you know, of her staff.
Q. After these meetings would take place, what would Mr. Chen do in terms of taking action based on the meetings?
MR. GALLAGHER: Objection. Lack of foundation, and calls for speculation.
A. I don't pay attention to, you know, other things, as I said, you know, because my, you know, main function or my main responsibility was to ensure the technical investigation, you know, move forward as soon as possible.
BY MR. SLATER:
Q. Did Mr. Chen give any instructions at these meetings? Other than you said he said, okay, you can buy that machine that you were asking about, did he ever give any other instructions?

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A. As I said, I don't --
MR. GALLAGHER: Objection.
Lacks foundation.
A. As I said, you know, my only focus, you know, was, you know, you know, for the part of the responsibility, you know, from my perspective.
BY MR. SLATER:
Q. Was Mr. Chen aware that at least as of July 27, 2017 there were people in your company that knew that NDMA was in valsartan that your company was selling?
A. He had no idea.
MR. GALLAGHER: Objection. No foundation.
BY MR. SLATER:
Q. How do you know he had no idea?
A. Because I told you, you know, as I told you before already, okay.
Q. Did anybody who either sent or received that e-mail ever tell Mr. Chen or tell someone else who told Mr. Chen about that?
MR. GALLAGHER: Objection.

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BY MR. SLATER:
Q. Do you know?
MR. GALLAGHER: Objection.
Vague, and lacks foundation.
A. As I said, I -- you know, I don't remember, or I don't know, you know, who else on that e-mail list, you know, what they did afterwards.
BY MR. SLATER:
Q. You don't know if Mr. Chen was aware that your company knew about the NDMA in the valsartan as of July 2017?
MR. GALLAGHER: Objection.
Vague, lacks foundation, and mischaracterizes the documents and testimony.
A. I'm pretty sure he -- you know, he didn't know. Otherwise, you know, he probably, you know, will talk to me.
BY MR. SLATER:
Q. Why do you say that?
A. Well, because, you know, if it's really, you know, you know, you know, you know, a big issue, you know, yeah,

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he will. You know, particularly, you know, this is, you know, right, related to an investigation of an impurity, right?
Mr. Chen, you know, you know, he is just at the very top. He wouldn't, you know, have those details, information, unless, you know, you know, you know, I became aware, and then I, you know, will report that to him, or somebody like from QA or whatever.
But as I said, you know, if people on that list, you know, they -- you know, they feel or whatever, you know, this is an issue, or they may not. As I said, you know, they may -- they may not, you know, or they think, you know, Mr. Lin's claim may be, you know, way exaggerated.
Q. Well, his claim wasn't exaggerated. He was 100 percent accurate about valsartan containing NDMA, correct?
MR. GALLAGHER: Objection.
Wait, Min.
THE WITNESS: Sorry.
MR. GALLAGHER: Objection.

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Vague, lacks foundation, calls for speculation, and mischaracterizes documents and testimony.
A. I think I answered this question, you know, several times, okay.
BY MR. SLATER:
Q. Did you tell Mr. Chen that in April of 2018 you told Mr. Lin, who worked for you, not to complete or not to issue -- rephrase.
Did you tell Mr. Chen at any time that in April 2018 you told Mr. -- rephrase.
Did you tell Mr. Chen at any time that in April 2018 you directed that a report that had been written regarding concern about nitrosamines in irbesartan, and you had instructed that that report not be issued because of the fact that the impurity was sensitive?
Did you tell Mr. Chen that?
A. No.
MR. GALLAGHER: Objection.
THE WITNESS: Sorry.

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MR. GALLAGHER: Objection. Outside the scope, vague, compound, and lacks foundation.
A. The answer is no.
BY MR. SLATER:
Q. You said that Mr. Chen was organizing these meetings. Based on your understanding and what you observed, was he very actively interested in what was happening with the contamination of valsartan with nitrosamines?
A. As I've said, that he is on top of the progress, okay? He didn't know, you know, all those technical details. It's not his job.
I just want to make sure -- yeah.
Q. I'm sorry.
How do you know he didn't know the technical details?
MR. GALLAGHER: Objection. Vague, and calls for speculation.
A. He is the CEO of the company. So if you talk to head -- like a CEO of

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Novartis, you know, he would -- would that person know the technical details of NDMA?
BY MR. SLATER:
Q. I don't know if -- I don't know, if it turned out that NDMA was contaminating one of their drug substances and that substance -- and the NDMA was carcinogenic, yeah, I would think the Novartis CEO would want to know everything about it, if you're asking me.
MR. GALLAGHER: Objection. Wait. Wait, Min. Objection. Vague, hypothetical, calls for speculation.
BY MR. SLATER:
Q. Do you know that --
MR. GALLAGHER: Just for the record, we've been going for an hour and 40 minutes now, and I'm sure the court reporter would love a break, but --
BY MR. SLATER:
Q. Do you know that Mr. Chen --
MR. GALLAGHER: -- your deposition.

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BY MR. SLATER:
Q. Do you know that Mr. Chen has a master's in chemical engineering?
A. That I --
MR. GALLAGHER: Objection.
A. Sorry.
BY MR. SLATER:
Q. Do you know that Mr. Chen has a background in chemistry or chemical engineering? Are you aware of that?
MR. GALLAGHER: Objection. Outside the scope.
A. I know he at least had a college degree, okay, but everything else I really didn't pay attention.
MR. SLATER: You can take a break now. Go off the record.
THE VIDEOGRAPHER: The time right now is 8:47 a.m. We're now off the record.
(Whereupon, a recess was taken)
THE VIDEOGRAPHER: The time right now is 9:05 a.m. We're back on the record.

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BY MR. SLATER:
Q. Do you know -- well, wait a second.
Do you know whether any record was made of Mr. Chen's interactions with other people in the company about the valsartan contamination?
A. I have no idea.
MR. GALLAGHER: Objection. Calls for speculation, and foundation -- lack of foundation.
BY MR. SLATER:
Q. Can you recall, other than discussing the equipment that you needed, anything else that you told Mr. Chen connected to the valsartan contamination with nitrosamines?
A. I'm sorry, say that again?
Q. Sure.
Do you remember anything you told Mr. Chen regarding the nitrosamine contamination of valsartan?
Earlier you told us you discussed some equipment you needed.

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Anything else?
A. As far as I can remember, you know, those are the items that I -- was the -- you know, was the main topic. Everything else I really, you know, do not recall.
But instrument, you know, was really an urgent needs because we need to, you know, have those instruments to be in place.
Q. What instrument --
A. Sorry --
Q. What instrument or instruments did you discuss the need for?
A. GC-MS, and also GC-MS/MS in particular, at least initially. And then later on there's also -- I think, you know, we discussed like some LC-MS equipment.
Q. Didn't you already have a GC-MS machine?
A. That --
MR. GALLAGHER: Objection.
A. Sorry, go ahead. I'm sorry.
You know, we were facing with

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thousands, you know, batches of valsartan need to be tested, okay, so a single, you know, GC-MS, you know, would not be sufficient, right.
And also that, you know, particular GC-MS also was needed, you know, to develop and optimize, you know, analytical methods. So we need to place the GC-MS also in the QC. Because in QC, in Chuannan CC there had been no GC-MS instrument, so we need to put these, you know, instrument into Chuannan QC site, right.
So eventually, you know, Chuannan QC site became the, you know, the main testing site for those, you know, thousands batches of commercial, you know, batches of the valsartan.
BY MR. SLATER:
Q. Was Mr. Chen told during these meetings that multiple customers of ZHP had since 2014 been complaining that there was unknown peaks and interference on chromatograms, and they were concerned about what impurities might be there, and that they

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kept asking for an answer from ZHP and couldn't get an answer?
MR. GALLAGHER: Objection. Lacks foundation, and mischaracterizes documents and testimony.
A. Such detail, you know, such technical details were never discussed, you know, at, you know, Mr. Chen's level.
BY MR. SLATER:
Q. Was there discussion about how your company should -- rephrase.
In these meetings with Mr. Chen, was there discussion about how your company should interact with the FDA?
MR. GALLAGHER: Objection. Outside the scope.
THE WITNESS: Pardon. Go ahead.
MR. GALLAGHER: Objection. Outside the scope.
To the extent you know personally, Mr. Li, you should answer.
A. Anything as far as I know, anything, you know, relating to interacting

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with regulatory agencies was taken care of by the RA department. Mr. Chen would not have, you know, such detailed knowledge, you know, how to interact.
BY MR. SLATER:
Q. How do you know that? Do you -- did you attend the meetings with the regulatory people that he attended?
A. I don't remember. But as I said, based upon my, you know, my observation, okay, he just would not be involved in too much, you know, operational details, okay. He's only pay attention to high levels, okay, like every --
Q. One of your very profitable drugs was contaminated with something that caused cancer. That's about as high level as it gets, right?
MR. GALLAGHER: Objection. Argumentative.
A. I don't want to comment on that, okay.
BY MR. SLATER:
Q. Do you know whether or not

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Mr. Chen ever discussed with anybody how your company should interact with the FDA?
A. I don't remember -- sorry.
MR. GALLAGHER: Objection. Outside the scope, and asked and answered.
A. I don't remember.
BY MR. SLATER:
Q. At any of these meetings that you attended, did Mr. Chen ever ask you, how did this happen, and ask for an explanation for how this could happen?
MR. GALLAGHER: Objection. Vague.
BY MR. SLATER:
Q. Time out. I'm going to ask the question again because counsel said it's vague, so in case, in case, you know, that objection will be sustained I'm going to ask the question again.
Did Mr. Chen ever ask you, how was it that our valsartan could be contaminated with a nitrosamine and we didn't know about it? Did he ever ask that

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question?
A. I don't remember specifically, okay, he -- like he specifically asked that question, okay. But I can tell you at least in one of those meetings like, like I explained to everyone, you know, you know, the root cause analysis as we put into this deviation report.
Q. When you say the deviation report, you mean the deviation investigation reports that were provided to the FDA?
A. Yes.
MR. GALLAGHER: Objection. Lacks foundation.
A. The deviation report actually, you know, you and I, we just went through, you know, an early draft version. Yeah, I think that -- that's the deviation, you know, investigation report.
But what you presented, you know, was only -- you know, looks like an early version. It's not the final, finalized version.
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BY MR. SLATER:
Q. Did you tell Mr. Chen that in multiple drafts the deviation investigation report stated that your company had insufficiently researched and studied the chemical processes, and then somebody made the decision to take that language out of the report before the report was finalized? Did you or anyone tell them that, to your knowledge?
MR. GALLAGHER: Objection. Vague, and argumentative.
A. I don't remember those details. But my guess is, you know, such details would not be discussed during those meetings usually.
BY MR. SLATER:
Q. Did you or anybody else in your presence tell Mr. Chen that your company failed to sufficiently research or study the chemical processes, and that's why your company didn't know that NDMA was a potential contaminant from the beginning?
MR. GALLAGHER: Objection.

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Vague, lacks foundation, and argumentative.
A. As I said, you know, you know, whatever the background information provided in the deviation, you know, in that deviation investigation report, you know, I remember that, that I, you know, as I said, I give a description or, you know, basically went through that some of those contents in the deviation, you know, introduction part.
BY MR. SLATER:
Q. Did anybody -- rephrase.
Did you or anybody else, to your knowledge, tell Mr. Chen that your company was aware that the valsartan your company was selling was contaminated with NDMA long before it came out in June of 2018 to the public?
MR. GALLAGHER: Objection. Vague, and lacks foundation.
A. As I told you, you know, I mean, people attended -- you know, I mean, basically, you know, we didn't know, I mean, you know, at a high level, before the events.

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BY MR. SLATER:
Q. What do you mean, "we didn't know at a high level"?
A. You know, for those people, you know, attending, you know, the meetings.
Q. Well --
A. As I said, nobody except Mr. Chen -- sorry, Mr., you know, Lin, as I said, he made some guess, you know, out of, you know, you know, some irbesartan, you know, experiment, right? He's making some -- his projections, you know.
Nobody else -- you know, nobody else, you know, know, you know, there was an issue, until, you know, June the 6th, 2018.
Q. Just to be clear, Mr. Lin stated July 27, 2017 that what he was seeing with irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite. That's what he said in the e-mail.
And you knew that because it was in the e-mail that was sent to you, so you had that information, correct?
MR. GALLAGHER: Objection.

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Compound, lacks foundation, and mischaracterizes documents.
A. As I told you before, you know, for some reason that e-mail just slipped through, you know. So I -- you know, I had no memory, I don't, you know, know until, you know, you just showed me a few days ago, like the day before.
BY MR. SLATER:
Q. Well, if you had no e-mail, why do you keep telling me that this was some sort of a guess or something else or speculation by Mr. Lin if you don't remember it?
A. Well, based upon -- you know, now, based upon the --
MR. GALLAGHER: Wait.
THE WITNESS: Sorry.
MR. GALLAGHER: Objection.
Argumentative, and asked and answered.
A. You know, it's basically, yeah, based upon that e-mail, yeah, now you provide to me, by reading through. Right? You provide me, you know, the day before, you

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know, that e-mail, right? Yeah, I just read through, you know, it looks like, you know, he's making his projections.
BY MR. SLATER:
Q. Well, he wasn't projecting regarding valsartan. He was stating it as a fact that it's known that NDMA occurs in valsartan when quenched with sodium nitrite.
And that statement in his e-mail was scientifically accurate, correct?
MR. GALLAGHER: Objection.
Lacks foundation, compound, and mischaracterizes documents.
A. As I told you, if you look through that e-mail, okay, the data that he had, okay, based upon -- you know, again, based on content of that e-mail, the data that he had were from the experiment with irbesartan, okay?
There's no -- there's no data mentioned with anything, like, related to, you know, valsartan, right?
I mean, can you see, you know, from the very beginning, go through this

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whole document? You know, I don't see it.
BY MR. SLATER:
Q. He didn't actually -- rephrase.
What he said was that he was seeing with the irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite.
He didn't need to present data in this e-mail because that was a fact he was reciting in the e-mail which was accurate.
A. No, no, no. The --
MR. GALLAGHER: Wait.
THE WITNESS: Sorry.
MR. GALLAGHER: Objection.
Lacks foundation, vague, and mischaracterizes the document.
A. The only data or external information or publicly available information related to valsartan, you know, if you can see, is related to that patent, right. So that patent is actually, you know, referring to, you know, impurity K in valsartan. Okay?
BY MR. SLATER:
Q. This was internal information

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that wasn't being shared with anybody from outside the company, this e-mail from July 2017. It's an internal e-mail, right?

A. Yeah, it is internal e-mail, yeah.

Q. And when -- rephrase.

When that e-mail states that NDMA occurs in valsartan when it's quenched with sodium nitrite, that's an accurate statement. That's actually the root cause of the NDMA contamination, right?

MR. GALLAGHER: Objection. Lacks foundation, and mischaracterizes the document.

A. I'm not sure exactly, you know, based upon -- you know, based upon that particular wording, you know.

But, you know, to me, you know, when he said quenching with, you know, valsartan, you know, quenching with sodium nitrite, right, the only -- as I said, you know, the available, you know, information, it looks like is the attachment of that external patent.

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Okay. That patent, if you look through it, it's only talking about, you know, component, you know, like impurity K and L, probably.

BY MR. SLATER:

Q. Would you be surprised if I was able to show you documentation that your company did chromatography and identified NDMA in valsartan prior to July 27, 2017?

Would that surprise you?

MR. GALLAGHER: Objection. Argumentative.

A. Yeah, I would be surprised if you say, because I don't -- you know, I'm not aware of that.

BY MR. SLATER:

Q. Would it be surprising to you if we were to show you documents indicating that there were people within your company that had figured out that there were nitrosamines, likely NDMA -- rephrase. Let me rephrase it.

I'm going to actually ask you even more directly.

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Did anybody in your company identify NDMA through chromatography prior to July 27, 2017 where you were made aware that it had been identified on the test?

A. Before -- I'm sorry. Before which date?

Q. Before the e-mail sent by Mr. Lin on July 27, 2017.

MR. GALLAGHER: Objection. Lack of foundation.

A. I was not aware.

BY MR. SLATER:

Q. Was anybody in your company aware of that, that --

A. I --

MR. GALLAGHER: Objection.

BY MR. SLATER:

Q. Was anyone in your company aware of a test result that you know of that showed NDMA in valsartan before July 27, 2017?

MR. GALLAGHER: Objection. Lack of foundation.

A. I don't know.

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BY MR. SLATER:

Q. To your knowledge, was anybody in your company disciplined in connection with the valsartan contamination with NDMA?

A. I have no knowledge.

MR. GALLAGHER: Objection.

THE WITNESS: Sorry.

MR. GALLAGHER: Lack of foundation, calls for speculation.

BY MR. SLATER:

Q. For example, did anybody lose their job?

MR. GALLAGHER: Same objection.

A. I don't know.

BY MR. SLATER:

Q. Was anybody reassigned?

MR. GALLAGHER: Same objection.

A. As I said, I don't know. I mean, this is not my job; this is human resources' job. I don't know.

MR. SLATER: Let's go, Cheryll, back to Exhibit 319, to the second page, please.

Actually, let's -- just to

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reorient, just stay there. Thank you.
BY MR. SLATER:
Q. Looking at Exhibit 319, it starts with a July 5, 2018 e-mail from Charles Wang to someone named Jim, and we just went through that e-mail a moment ago.
MR. SLATER: And we can scroll down to the second page of that e-mail, please. No, no, that e-mail. Sorry. Thank you. Go to the bottom of the page, please. Yes.
Q. Okay. Now, it's actually -- let me ask you this question, actually. Where -- rephrase.
Where Mr. Wang told Jim that a friend of his was looking for a consultant in the United States to help them define their product at FDA, at that point you were aware and you had authorized Mr. Wang to find an independent consultant for you?
MR. GALLAGHER: Are you done? Objection. Vague.
A. It looks like, yeah, we asked him probably, you know, yeah, to go ahead and

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try to find.
MR. SLATER: Okay. Now let's go up to the next e-mail, please. Thank you.
BY MR. SLATER:
Q. In response to Charles Wang's e-mail on July 5th at 1:50 p.m., Jim MacDonald, we can see his e-mail, writes back to Charles.
Do you see that?
A. Yeah, mm-hmm.
Q. He says, "Good to hear from you.
"I am at the beach with my family. I'll be back in the office from Monday and" I will give you -- "and will give you a call. It will be good to catch up.
"Best regards, Jim."
So that was the response, correct?
A. Mm-hmm.
MR. SLATER: Okay. Now let's scroll to the next e-mail, and I think that the very beginning of that e-mail

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is at the bottom of the first page. Perfect.
Q. Charles Wang then responds on July 5, 2018 at 10:27 p.m., so this is still on the same day as the first e-mail.
Do you see that?
A. Yeah, mm-hmm, it's July 5th, yeah, 2018.
Q. Writes to Jim MacDonald.
A. Mm-hmm.
Q. And he says, "Hi Jim, Nice to hear from you. Hope everything is going well."
MR. SLATER: You can scroll down now, Cheryll, so we have the whole e-mail.
Q. Okay. I'll start over.
The e-mail reads, "Hi Jim, Nice to hear from you. Hope everything is going well.
"Sorry to disturb you during your vacation. My friend's company will have a face-to-face meeting with FDA to debit if they should recall their product in US market

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next Thursday and likes to get some advice from people like you quickly."
Do you see that?
A. Yes.
Q. And that's consistent with what you had discussed with Mr. Wang, that you were looking to bring in another consultant to help prepare for that meeting, correct?
MR. GALLAGHER: Objection to the extent it mischaracterizes testimony.
You can answer.
A. As I -- yeah, as I said, yeah, it looks like, yeah, we, you know, we -- basically we took his recommendation to looking for, yeah, an expert on the -- you know, yeah, on that particular, you know, carcinogenicity area, yeah.
BY MR. SLATER:
Q. And again, as you said earlier, you had a lot of trust in Mr. Wang, considered him to be a reliable expert, so you asked him to go find you the most qualified person he could find basically,

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right?
A. Yeah, it looks like.
Q. This e-mail continues -- rephrase.
The e-mail continues, "Not sure if you heard Huahai Pharma Group, one of the largest generic drug company in China with a branch in US (Cranberry, NJ). Li knows their US CEO as well."
Do you know who Li is?
A. I have no idea.
Q. Do you know if that's you that's being referred to?
A. Based upon the content, it should not be me.
Q. So the -- rephrase.
The e-mail continues. "Li knows their US CEO as well. Huahai has a product in US market with the maximum daily dose of 320 milligrams, which recently was found containing high Nitrosodimethylamine (NDMA, not know exactly how much but around 30 parts per million)."
I want to stop there.

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Do you see the reference to 30 parts per million?
A. Yes.
Q. And we've been through the test results already earlier in your deposition. You would agree with me that 30 parts per million is actually on the very low side compared to the ranges of NDMA that was found in the zinc chloride process valsartan, correct?
MR. GALLAGHER: Objection. Vague.
A. The average, as far as I can remember, is somewhere around like 55 or maybe, you know, between 55 and 60 ppm average.
BY MR. SLATER:
Q. That's your best recollection?
A. Yes.
Q. We went through the list, the numbers ranged up as high as 188.1, 165.1, 172.3, there were some -- some very high numbers on that chart that we went through the other day, correct?

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MR. GALLAGHER: Objection. Vague, and lacks foundation.
A. Yes. But these are, you know, very small fractions. We also have very low numbers, like single digit numbers.
BY MR. SLATER:
Q. Continuing in the e-mail, Charles Wang writes, "Their client in EU" -- and that would be the European Union?
A. Yeah, it should be.
Q. And when they talk about -- rephrase.
When he speaks about your client in the EU, he's talking about Novartis, right?
MR. GALLAGHER: Objection. Lack of foundation.
A. I would say probably, but I wouldn't be 100 percent. It probably is Novartis.
BY MR. SLATER:
Q. It says, "Their client in EU said it should be at 0.3 parts per million based on TD50 calculation."

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That was what Novartis said, correct?
A. That was Novartis said it at one point, yeah. As I said, you know, some early discussion with Novartis, you know, they were basing the TD50 from a primate, but then the, you know, the threshold would be lower, yeah.
But this one, as I said, it looks like based upon the rodent, you know, studies.
Q. And the 0.3 that Novartis recommended actually is the number the FDA ended up agreeing on as well, correct?
MR. GALLAGHER: Objection. Outside the scope, and lack of foundation.
A. I would say eventually. You know, at a very early stage, you know, FDA did take this as an interim spec, and then the, you know, the official allowable intake at that time, you know, as I said, was -- should be absent.
But then, you know, after, you

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know, maybe about a year or so, you know, now FDA basically broadened that to, you know, 0.3 ppm.
BY MR. SLATER:
Q. The e-mail continues. "They would like to know if they can argue to set limit higher based on NDMA is considered a Class 2A carcinogen (limit at threshold of toxicological concern of 1.5 micrograms per day) and the longest duration of human exposure in US will be less than 3 years."
Do you see that?
A. Yes.
Q. And we went through earlier the e-mail where Charles Wang actually told you that NDMA actually should be a class A -- a class -- rephrase.
And we went through earlier the e-mail where Charles Wang told you he thought NDMA met the criteria for a Class 1 carcinogen. We saw that e-mail a few minutes ago, right?
MR. GALLAGHER: Objection. Lack of foundation, and to the extent

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it mischaracterizes the document and testimony.
A. Yes, we looked through that document. But as I indicated, okay, that's the MSDS, you know, from that particular chemical company, okay.
Based upon today's knowledge, you know, if they talking about that classification based upon IARC, you know, that information was incorrect, okay. The IARC categorization as of today is still 2A, Class 2A.
BY MR. SLATER:
Q. The e-mail continues. "Let me know if your company can help. I will ask them to contact you directly and send you more details.
"Thanks a lot for your help and enjoy your vacation. Best, Charles."
And that's how that e-mail ended, correct? Do you see that?
A. Yes.
MR. SLATER: Let's go now, Cheryll, to the next e-mail in the

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chain which starts about a third of the way down the first page of this page. Perfect.
Q. On July 6, 2018, the next day, at 11:11 a.m., Jim MacDonald responds.
Do you see the e-mail?
A. Yes.
Q. And we now can see where Jim MacDonald comes from, he has a company called Synergy Partners Research & Development Solutions, and he's listed as James S. MacDonald Ph.D, Founding Partner, right?
A. Yes.
Q. Jim MacDonald writes, "Charles, I'm afraid I can't be of much help in this case particularly on this time scale.
"NMDA (or dimethylnitrosamine) is a pretty well-known toxin and animal carcinogen with lots of discussion on permissible levels in drinking water and products. Even though the compound is found in cured meats and some groundwater, the body of evidence on this suggests pretty clearly that this is a likely human carcinogen at

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sufficient exposures."
Do you see that?
A. Yes.
Q. And a likely human carcinogen means something that likely causes cancer in humans, that's what that means, correct?
A. I think I went through this topic many times. It is a, you know, probable human carcinogen.
Q. He continues. "The argument that the company would have to make to keep this product on the market will be very difficult with this profile. I'm not exactly sure where one would begin given the very high levels you think they are seeing."
I want to stop there.
When he refers to the very high levels, we just saw in the earlier e-mail that he was quoted a level of 30 parts per million in the prior e-mail, correct?
MR. GALLAGHER: Objection. Lack of foundation, and calls for speculation.
A. Let me read through, okay?

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BY MR. SLATER:
Q. Just so you understand my question, when he refers to the very high levels you think they are seeing, I had just shown you in the prior e-mail that Charles Wang, or Wang, had quoted him 30 parts per million.
Do you remember that?
MR. GALLAGHER: Objection. Lack of foundation, and calls for speculation.
A. Yes, I remember that 30 parts per million number, yes.
BY MR. SLATER:
Q. So this toxicologist -- rephrase.
So this toxicologist who Charles Wang was going to on your behalf was actually telling you that 30 parts per million were very high levels, and we've already established the levels were actually higher, correct?
MR. GALLAGHER: Objection. Lack of foundation, compound, and

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vague.
A. The average value is higher than 30 ppm. But, you know, there was, you know, certain numbers of batches that were below 30 ppm.
BY MR. SLATER:
Q. You told me the average a moment ago was, your best recollection, was 55 to 60 parts per million, correct?
A. Yes.
Q. And going back to the math that we did before, if it was 60 parts per million for a 320-milligram pill, that would be 19,200 nanograms, correct? 60 times 320, right?
MR. GALLAGHER: Objection. Calls for speculation and expert testimony.
Are you asking him to do the calculation? Do you have a calculator?
BY MR. SLATER:
Q. You certainly don't -- you can agree with me or you can check it yourself,

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or you can disagree with my math.
A. So your calculation based upon what, 60 ppm or --
Q. Right, 60 ppm for a 320-milligram pill would be 19,200 nanograms of NDMA, correct?
MR. GALLAGHER: Same objection.
A. 19,000 -- wait a second. You said 19,000 -- what is the rest of the number?
BY MR. SLATER:
Q. 19,200.
A. 200 nanogram.
Q. Right. That's the number, right?
A. Probably. I mean, you know, I didn't check myself. But it's probably on the ball park.
Q. And if it was 60 parts per million, the average that you told me, and a 160-milligram pill, we do 60 times 160 and come up with 9,600 nanograms, correct?
MR. GALLAGHER: Same objection.
A. Hold on, let me double-check.

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So 60, right, 60 times 320.
Yeah, 19,200 nanogram, yeah, for the 60 ppm for 320 milligram, yeah.
BY MR. SLATER:
Q. The ultimate limit that the FDA set was 96 nanograms, correct?
A. Yes.
MR. GALLAGHER: Objection. Outside the scope.
BY MR. SLATER:
Q. So if we take 19 -- rephrase.
So if we take 60 parts per million -- rephrase.
If we take a 320-milligram pill, which would be 19,200 nanograms of NDMA, and we divide that by 96, it comes to 200.
So that would be 200 times the limit that the FDA ended up setting, correct?
MR. GALLAGHER: Objection. Lack of foundation, and outside the scope, and calls for expert testimony.
A. The calculation, it looks like it's correct. 19,200 divided by 96 is 200.

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BY MR. SLATER:
Q. And even for a 160-milligram pill, we'd be talking about 100 times the FDA limit of 96 nanograms, right?
MR. GALLAGHER: Objection. Lacks foundation, outside the scope, and calls for expert testimony.
A. The calculation seems to be correct.
BY MR. SLATER:
Q. And that's -- rephrase.
And those numbers are based on 60 parts per million, which is double the 30 parts per million that this toxicologist who was being consulted on your behalf said were already very high levels, correct?
MR. GALLAGHER: Objection. Lacks foundation, vague.
A. I mean, whatever it says in the e-mail, you know, I mean, it's there.
BY MR. SLATER:
Q. Reading the e-mail further, Mr. -- rephrase.
Reading the e-mail further,

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James MacDonald says, "I think the strategy I would probably recommend would be to come up with a CMC plan to remove the contaminant (at least to minimally detectable levels) while they recall the existing product and re-formulate. I expect this is not what they would want to hear but, unless there is a compelling reason to leave this product on the market (e.g.: only product available to treat a serious, life-threatening disease), I would expect the FDA would ask for a recall. I'd be interested to know what happens at the FDA meeting. These things are always very difficult to predict - but this is not a good position for this product in my view.
"Hope all is well with you.
"Best regards, Jim."
Do you see that?
A. Yes.
Q. And Mr. Wang relayed to you that he had spoken with Jim MacDonald and what the result of that interaction had been after he had heard from Mr. MacDonald, correct?

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MR. GALLAGHER: Objection. Lacks foundation.
A. I don't remember the details. He probably talked to me verbally, at least.
BY MR. SLATER:
Q. He certainly would have let you know, hey, I spoke to Jim MacDonald, the guy I thought could help us, unfortunately this is the response I got.
He at least would have let you know what happened and what the information was, right?
MR. GALLAGHER: Objection. Lacks foundation, calls for speculation.
A. I just said I don't remember the detail, okay?
And one thing, you know, you know, I think I need to maybe provide, you know, some of the, you know, background, okay?
You know, even in this ongoing, right here it's mentioned, you know, this like, you know, upcoming meeting with FDA,

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okay, so during that meeting, you know, FDA still asked us to be on hold with regard to our, you know, question whether we should do the recall immediately, okay?
So the thing is, you know -- or the fact, you know, indicate at that time FDA still was not sure, you know, obviously, you know, because by considering, you know, the potential drug shortage. So FDA still wasn't sure, you know, what a level or an interim limit should be set, you know, to -- you know, potentially to allow some batch.
For example, you know those batch below 30 ppm, you know, still temporarily remain on the market, you know, to address, you know, the potential, you know, drug shortage issue.
MR. SLATER: Going now to the top of the page, please.
BY MR. SLATER:
Q. The next e-mail in this document is July 17, 2018, Charles Wang writes to Jim MacDonald.
Do you see that?

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A. Mm-hmm.
Q. He says, "Hi Jim. You may have already seen this," and then he has the link to Press Announcements.
"It is exactly like you expected, and I agreed with your call.
"Thanks again for your help. Keep in touch for the future collaboration opportunity."
Do you see that?
A. Yes.
Q. And this would have been the announcement of the recall, correct?
MR. GALLAGHER: Objection. Lacks foundation.
A. That's July 17th.
So can we go down? Okay.
So the previous one was the July 6th. So whether this is related to recall, you know, we can take a look, you know.
Can we, you know, take a look of this announcement?
///

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BY MR. SLATER:
Q. I'm just asking if you agree with me that he would have been talking about the recall at that point, on July 17, 2018.
MR. GALLAGHER: Objection. Lacks foundation.
A. I mean, eventually FDA, yeah, basically agree, you know, with us, you know, at that time, you know. They, you know, allow us to, you know, to initiate the recall, you know, for those batches, you know, impacted. Yeah.
But I'm not sure whether, you know, if this particular July 17th. But it looks like, but, you know -- but essentially, as I said, that during the -- you know, that upcoming meeting, you know, a teleconference meeting with FDA, you know, FDA at the time still asked us to hold on the recall.
BY MR. SLATER:
Q. Where -- rephrase.
Charles Wang, as we can see in this e-mail, told Jim MacDonald, "I agreed with your call."

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MR. GALLAGHER: Objection. Lacks foundation.
BY MR. SLATER:
Q. Did Charles Wang tell you that he agreed with Jim MacDonald's call on what should happen here?
MR. GALLAGHER: Objection. Lacks foundation.
A. So the e-mail, you know, yeah, says whatever, yeah, he says. I mean, as I told you, you know, from the very beginning, you know, after, you know, you know, you know, you know, we determined the root cause, you know, we determined -- you know, we developed a method and we, you know, determined the range or the average of the contents, as I said, we immediately, you know, approach FDA, ask whether we should do, you know, immediate recall, you know, as I said.
But it looks like, you know, it's probably, based upon the contents, you know, the likely scenario would be, yeah, by July 17th FDA made this announcement, and

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also we also received, you know, FDA's instruction, you know, to start recall, as we have been asking FDA, you know, you know, whether we should do, you know, immediately or as soon as, you know, it should be done.
MR. SLATER: Cheryll, if you could scroll down a little bit more, please. Perfect.
BY MR. SLATER:
Q. I want to go back to the e-mail from July 6th where it's documented that Dr. MacDonald told Charles Wang that the body of evidence suggests pretty clearly that this is a likely human carcinogen at sufficient exposures. Do you recall we talked about that a few moments ago?
A. Yes.
Q. Charles Wang told you the same thing, right?
MR. GALLAGHER: Objection. Lacks foundation, and I'm going to object to outside the scope.
Adam, I've let you ask questions about this --

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MR. SLATER: I don't know why you're saying this, Patrick. This is ZHP's evaluation of knowledge of the health risks of nitrosamines, Topic 36.

MR. GALLAGHER: Nobody from -- nobody from ZHP is on this e-mail. Nobody from ZHP is on this e-mail. He said he doesn't recall talking to him.

MR. SLATER: Are you going to testify now? Relax. Are you going to testify now?

MR. GALLAGHER: No, I'm objecting it's outside the scope. You told -- you just said ZHP's knowledge. Nobody from ZHP is on this e-mail.

MR. SLATER: Are you testifying now --

MR. GALLAGHER: You're trying to put words in Dr. Wang's mouth of what he told Dr. Li. He said he doesn't recall. I'm just objecting outside the scope. Ask your questions.

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MR. SLATER: Would you like to testify? We could place you under oath if you want? I mean, you're literally -- you realize how far over the line what you just did is. Please don't do that again. I'd really appreciate it.

BY MR. SLATER:

Q. Did Charles Wang tell you that it was clear to him that NDMA was a likely human carcinogen at sufficient exposures when you were consulting with him?

MR. GALLAGHER: Objection. Lack of foundation.

A. As I said, I don't remember, you know, such details, okay. But based upon, you know, the e-mail communication with him, yeah, he indicated, yeah, it's a likely, you know, human carcinogen, okay, based upon, you know, the results from animal studies. Right. It's likely, you know, it's a probable, you know, it's -- you know, it's the same meaning.

I mean, just like in, you know,

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IARC, you know, you know, classification to be, you know, 2A, you know, basically means, you know, you know, it's a potential or probable, you know, to human based upon, you know, animal, you know, you know, studies.

BY MR. SLATER:

Q. Did you or anybody from your company ever tell the FDA that a toxicologist who was hired by your company advised you that NDMA was a likely human carcinogen?

MR. GALLAGHER: Objection. Outside the scope, and calls for speculation.

A. I don't remember, you know --

MR. GALLAGHER: And lack of foundation.

MR. SLATER: Just bear with me for a second. I think I misplaced a document. Sorry, everyone, but I'm a little confused.

Okay. I got it. Okay.

We can take this one down. And let's go to -- the last one was 319, right? Let's go to Exhibit 320, which

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starts with CHARLESWANG000164.

(Whereupon, Exhibit Number ZHP-320 was marked for identification.)

MR. SLATER: And what I'd like to do is go to page -- the Bates number is 179. Go to the very top. I just really want to go to the very top of the page, actually.

BY MR. SLATER:

Q. Do you see at the top it says, "WeChat communication with Min Li and Jun Du, July 8, 2018"?

A. Okay.

Q. Do you see that?

A. Mm-hmm.

Q. And do you recall that you communicated through WeChat with Charles Wang and -- or Charles Wang and Jun Du?

A. I don't recall the details.

Q. Why was Jun Du involved in any of your interactions with Charles Wang?

A. Why? I mean he's the -- you know, first of all, he's the executive vice

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president of the company, and also he's the head of Huahai in the US and also, you know, the Prinston Pharma.
Q. Did you tell Jun Du the feedback you got from Charles Wang after he had communicated with Jim MacDonald in early July 2018?
MR. GALLAGHER: Objection. Vague, and lack of foundation.
A. I'm sorry, could you repeat the question?
BY MR. SLATER:
Q. Sure.
Did you tell Jun Du the feedback you got from Charles Wang after he had communicated with Jim MacDonald in early July of 2018?
A. I don't remember -- sorry.
MR. GALLAGHER: Objection. Lack of foundation.
A. I mean, as I said, I don't remember, you know, such details, but at a such -- you know, at a certain point, you know, he came to know.

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BY MR. SLATER:
Q. At some point you told him?
A. I don't remember whether I told -- told him or Charles Wang told him. I just don't remember, you know, you know, the details.
Q. Now, what I want to do is go to the very first page of this document now, the Bates number 164. Let's go back up to the top.
And this was a draft report that Charles Wang provided.
MR. SLATER: Cheryll, if you could scroll down to the bottom half of the page just so we can show that.
Q. And you recall Charles Wang provided some potential draft reports for you about safety assessments for NDMA?
MR. GALLAGHER: Objection. Lack of foundation.
A. There are probably some draft, yes.
BY MR. SLATER:
Q. What I'd like to do now is --

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MR. SLATER: Cheryll, can you go to page 10 of this? The Bates number is 173, please.
Q. There's a table that we see on this page, and it says, "Table 1: Reasonable Worst-Case Estimates of Daily Intake of NDMA by the General Population in the Sample Country."
Do you see that?
A. Yes.
Q. Do you know where that table came from?
MR. GALLAGHER: Objection. Lack of foundation.
A. Right now I don't, just don't remember the details.
BY MR. SLATER:
Q. To the ex -- well, rephrase. Or withdrawn actually.
Okay. Let's -- just so that you can be familiar with this table, you see that it talks about how people can be exposed to NDMA and -- during the day, and it lists on the left-hand column things like air,

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water, food, indoor air, groundwater, beer, and shampoo.
Do you see that?
MR. GALLAGHER: Objection. Vague, and lack of foundation.
A. It is listed there.
MR. SLATER: Okay. Let's take that down now and go to Exhibit 210.
Give me a second. You know, I apologize, Cheryll, can you go back to the prior exhibit, please? I'm sorry to make you go back, it's Exhibit 320.
If you could, go back, go back to page Bates number 182, please. It's page 19 of the report, of the draft.
BY MR. SLATER:
Q. This is at the end of that draft report that Charles Wang provided. Do you see this, he provided a biography?
A. Yes.
MR. GALLAGHER: Objection. Lack of foundation, and mischaracterizes testimony.

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MR. SLATER: What's the lack of foundation? It's a document you produced to us.
MR. GALLAGHER: The document Charles -- it came from Charles Wang. You haven't established with the witness or what --
MR. SLATER: What haven't I established? I'm sorry.
MR. GALLAGHER: You don't know what the document is. It's a document that was produced from Charles Wang.
MR. SLATER: We already established it's a draft that was -- of a report that was provided dated June 15, 2018. We already went over that with the witness. We already established that's what they were getting from Charles Wang.
MR. GALLAGHER: I don't think you established where it came -- it's a document that was produced from Charles Wang, and it's dated June 15, 2018. I don't think you've

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established anything else about this document.
MR. SLATER: Okay.
BY MR. SLATER:
Q. Looking now at the biography that Charles Wang put in there, I just went through this for a moment, and he gives some of his background and he says that, around the middle, he was the "Vice President of Drug Safety and Regulatory Affairs at Hua Medicine, Limited, a US VC funded biopharmaceutical company in China."
A. I'm sorry, where that word?
Q. Right in the middle of the biography.
A. Okay. Dr. Wang, okay. Was the vice president. Let me read through.
(Witness reviewing document.)
A. Yeah, okay. Yeah.
Q. Then it says -- rephrase.
It says that he was "Director of Toxicology at Johnson & Johnson PRD," whatever that firm is, and "Senior Scientist at Novartis Pharmaceutical Corp. in the

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United States."
Do you see that?
A. Yes.
Q. Do you know why this doesn't list the fact that he was currently working at GlaxoSmithKline?
MR. GALLAGHER: Objection. Calls for speculation.
A. I have no idea.
MR. SLATER: All right. Now we can go back to the other exhibit. Thank you, Cheryll. Exhibit 210.
You know what? I lied again. I'm sorry. If you could go back to page 10 again of the other document, I'm sorry. I'm trying to make life difficult tonight for you.
BY MR. SLATER:
Q. Just above the table that we were discussing a moment ago, there's a line that says. "The worst-case estimation of daily intake of NDMA from different sources by general population at different age are listed below." And it says "[66]."

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And what I'd like to do, if we could. Is go to the references at the end of the report, and it's page 14, the Bates number is 177, to see what reference 66 is and where that table came from.
And you see reference 66?
A. Yes.
Q. It's a citation from the "Concise International Chemical Assessment Document 38, N-nitroso dimethylamine," which is NDMA, and it gives the authors' names, and it says it was from the World Health Organization in Geneva 2002, page 13.
Do you see that?
A. Yes.
MR. SLATER: Let's try this for the fourth time. Can we please go to Exhibit 210 now. Exhibit 210 is the Deviation Investigation Report.
And let's scroll down to make sure we have exactly which it is and what the date is. Perfect.
Q. And it's dated -- it says "Preparation Date: November 5, 2018," and

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then on the next page there's a list of signatures, report, review and approval, showing this was signed and finalized, correct?
A. Yes.
Q. And the deviation investigation report, this is a document that's laying out, among other things, the root cause and the significance of the contamination, correct?
MR. GALLAGHER: Objection to the extent it mischaracterizes the document.
A. It investigate the root cause or the likely root cause.
BY MR. SLATER:
Q. This is -- rephrase.
This is a document that's supposed to be fully accurate, right?
A. Based upon the knowledge at the time.
Q. This document is supposed to be fair and balanced in terms of providing information, right?
MR. GALLAGHER: Objection.

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Vague.
A. As I said, to the best knowledge available at that time.
BY MR. SLATER:
Q. Would you agree that this document should be an honest, scientifically rigorous document in terms of its analysis?
MR. GALLAGHER: Objection.
Vague.
A. Again, I said, you know, it's to the best knowledge, you know, of the authors at the time.
MR. SLATER: Cheryll, let's go, if we could, to page 10 of 236, please, the very top.
By the way, everyone, I have zero idea about time, so I don't know where you're at. I'm about to start in on this document, so now would probably be a good break time if we're at that point.
MR. GALLAGHER: I think we're just a little bit over an hour, so I'll leave it to you.

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MR. SLATER: Let's do that, because otherwise we'll break up in the middle.
MR. GALLAGHER: Okay.
MR. SLATER: So let's take a break.
How long do you want?
MR. GALLAGHER: Dr. Li, how long would you like for a break?
THE WITNESS: 15 minutes. Or maybe we come back at, what, 10:25?
MR. GALLAGHER: Sounds great.
MR. SLATER: Whatever you want. Sounds good.
THE VIDEOGRAPHER: The time right now is 10:09 a.m. We're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time right now is 10:27 a.m. We're back on the record.
BY MR. SLATER:
Q. Looking here at the deviation

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investigation report, this is Section 3.1.2, titled "NDMA Physiochemical Characteristics and Toxicological Evaluation of NDMA."
Do you see that?
A. Yes.
Q. The toxicological evaluation would be the part of the report where you got consulting services from Dr. Wang, right?
A. Yeah, it should be.
MR. SLATER: And let's turn, if we could, to the next page. Scroll up a little bit. A little more. Thank you.
Q. Looking now at page 11 of this report, you can see that there's a citation to something that was stated in the report to the Concise International Chemical Assessment Document 38 on NDMA, which we just saw before was cited in Dr. Wang's report, correct?
A. Yes.
Q. And one thing to be clear -- rephrase.
To be clear, ZHP would only cite scientifically reliable literature in

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this report, correct?
A. As I said, again, you know, based upon the best knowledge, and also, like you said, you know, this data is likely, you know, yeah, from, yeah, Dr. Wang's report, yes.
Q. Would ZHP cite literature or articles in this report that it did not believe was scientifically reliable?
A. It shouldn't.
MR. SLATER: Let's turn to the next page, page 12 of this report.
Q. We can actually see that that table that was cited in Dr. Wang's report and cited to that World Health Organization study is also actually found right here in the deviation investigation report, correct?
A. Yes.
MR. SLATER: Let's scroll down a little bit.
Q. There's a section titled "Animal Toxicity Studies," and it says in part --
MR. SLATER: Scroll down a

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little more, actually. Perfect.
Q. Under the "Animal Toxicity Studies" section, it says in part in that second paragraph, "Carcinogenicity studies in animals demonstrated that NDMA is carcinogenic. However, no evidence is available to confirm that NDMA is carcinogenic in humans. Nevertheless, NDMA is considered a probable human carcinogen based on projection from the animal studies."
And that's the -- that's what your company stated in this deviation investigation report, correct?
A. Yes.
Q. Now, we had talked a moment ago that the table up above came from the World Health Organization study, the Concise International Chemical Assessment document regarding NDMA.
Do you recall that?
A. Yes.
Q. And what we can do now is we can take this document down, and we can go --
MR. SLATER: I guess -- I don't

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know what the next exhibit would be. Is it 321?
THE STENOGRAPHER: Yes, it is.
MR. SLATER: Okay. Let's go, Cheryll, to Exhibit 321, the actual Concise International Chemical Assessment Document 38 regarding NDMA that's cited here in the deviation investigation report. Thank you.
(Whereupon, Exhibit Number ZHP-321 was marked for identification.)
BY MR. SLATER:
Q. And you can see that that's the title.
MR. SLATER: And if you can scroll down, Cheryll, just to confirm the date of it at the bottom, please. Perfect.
Q. You can see the "World Health Organization, Geneva, 2002," correct?
A. Yes.
Q. Let's first, just to be sure -- rephrase.

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MR. SLATER: Turn, if you could, Cheryll, to page 1. It's a couple pages ahead.
And you see there's a section that says -- rephrase. Stop, stop, stop, stop.
Q. You see it says "Procedures," correct?
A. Yes.
MR. SLATER: Scroll down, please, Cheryll, so we capture the last two paragraphs on this section. Perfect.
Q. You can see that the second paragraph under the Procedures talks about how the first draft was prepared. It says, "The first draft is based on existing national, regional, or international review." And there's more information.
Do you see that?
A. Yes.
Q. And then the next paragraph says, "The draft is then sent to an international peer review by scientists known

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for their particular expertise and by scientists selected from an international roster compiled by IPCS through recommendations from IPCS national Contact Points and from IPCS" participation -- "participating institutions."

And peer review is an important thing in scientific literature because that's one of the important stamps of reliability for scientific literature, correct?

A. Yes.

MR. SLATER: Let's go now, Cheryll, if we could, to page 13. 13. The very top. Perfect.

Q. We can see here on page 13 that the table that we've been talking about that was copied into Dr. Wang's report and into the deviation investigation report is found in this article as cited.

Do you see that?

A. Yes.

MR. SLATER: Let's go now, Cheryll, to page 26, if we could. And if you could go down to the last part

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of that page, Section 12, there's a little paragraph there. On this page, just go to the bottom of the page.

Oh no. I'm getting a feeling like a frozen computer issue is happening. "Frozen." I just got a text from Cheryll, "Frozen."

Could we go off for a moment just while she fixes her issue, please?

MR. GALLAGHER: Sure.

THE VIDEOGRAPHER: The time right now is 10:35 a.m. We're now off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time right now is 10:40 a.m. We're back on the record.

BY MR. SLATER:

Q. I want to go through the document a little bit, this article. First we'll start in Section 12 titled "Previous Evaluations By International Bodies."

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And this states, "NDMA has been classified by the International Agency for Research on Cancer (IARC, 1987) as a 'probable human carcinogen (Group 2A),' based upon sufficient evidence of a carcinogenic effect in experimental animal species and the demonstrated similarities in its metabolism by human and rodent tissues."

Do you see that?

A. Yes.

Q. And in terms of the risks to humans as compared to animals, you certainly don't disagree that there are similarities in the metabolism of humans and rodents as stated here, you certainly don't disagree with that, right?

A. Whatever that statement says.

Q. Let's go now to page 16. Page 16, heading 8.4, it says "Carcinogenicity," and again that's whether something causes cancer, right?

A. Yes.

Q. And if you go a little further down actually, let's go to Section 8.5,

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perfect, Section 8.5 is "Genotoxicity and related end-points."

And genotoxicity is where -- well, you can explain it. Tell me, what's your understanding of genotoxicity?

A. Any chemical substances, you know, where they chemically react with DNA.

Q. And this states in numerous -- well, rephrase. Let me just take a step back.

NDMA is a genotoxic substance, correct?

MR. GALLAGHER: Objection. Vague, and calls for expert testimony.

A. It is.

BY MR. SLATER:

Q. NDEA is also a genotoxic substance, correct?

MR. GALLAGHER: Same objections.

A. Yes.

BY MR. SLATER:

Q. This section states, "In numerous studies conducted in vitro in

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bacterial and mammalian cells, there has been overwhelming evidence that NDMA is mutagenic and clastogenic (reviewed in IARC, 1978; ATSDR, 1989). Increased frequency of gene mutations, chromosomal damage, sister chromatid exchange, and unscheduled DNA synthesis have been observed in a wide variety of cell types, in assays conducted in the presence or absence of metabolic activation. Positive results have been observed in human as well as rodent cells."

Do you see that?

A. Yes, that's what it said.

Q. Then it says, "Similarly, clear evidence of genetic effects has also been observed in in vivo studies," correct?

A. In vivo studies, mm-hmm.

MR. SLATER: Let's go now, if we could, Cheryll, to page 21. This is Section 9, "Effects on Humans." And if you could scroll down, Cheryll, to the second paragraph under there.

Q. The second paragraph starts out, "Relevant epidemiological studies

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include case-control investigations in which the potential risks of cancer of the stomach," and I'm going to skip the citation names for now, "upper digestive tract, and lung associated with the ingestion of NDMA have been assessed."

So they're citing to studies that have looked at whether or not there's a risk to humans from NDMA, correct?

A. It looks like.

MR. SLATER: Let's go now to the other -- the second column at the top, please. Let's get that top half of the page. Perfect.

Q. Continuing this section regarding effects on humans of NDMA, it says, "In three of four case-control studies, there was a positive relationship with evidence of exposure-response for the intake of NDMA and gastric cancer."

You see that citations, there's three articles cited right there?

A. Yes.

Q. Then if we go a little further

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down, it says, "In two case-control studies in which matching or control for confounders was rather more extensive than that for the investigations of gastric cancer mentioned above, three [sic] were clear exposure-response relationships for NDMA and lung cancer."

Do you see that?

A. Yes.

Q. And what they're talking about here with this -- this -- rephrase.

And what they're talking about here is that there are epidemiologic studies that have been done showing that there is a clear relationship between NDMA and humans developing certain cancers, correct? That's what they're talking about?

MR. GALLAGHER: Objection. Foundation, calls for expert testimony.

A. Well, they're talking about some, like you said, epidemiology, you know, studies.

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BY MR. SLATER:

Q. It continues, "In almost all studies, associations between the cancers of interest and nitrate, nitrite, and NDMA were examined; results were relatively consistent in this regard, with there being an association with cancer most commonly with NDMA"; and then it says, "results for nitrite were mixed, and there was an inverse association with nitrate."

Do you see what I just read?

A. Yes.

Q. And -- rephrase.

When they talk about an association with cancer most commonly seen with NDMA, they're talking about cancer in human beings, correct?

MR. GALLAGHER: Objection. Calls for expert testimony, and outside the scope.

A. I'm not sure they are purely talking about, you know, with cancer in human, just based upon, you know, this statement.

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BY MR. SLATER:
Q. This section is "Effects on Humans," and it's relating the results of epidemiologic studies.
Those would be studies of cancer in human beings, correct?
MR. GALLAGHER: Objection. Calls for speculation, and lack of foundation.
A. Let me read through that part, okay?
BY MR. SLATER:
Q. You understand the question is, these are epidemiologic studies regarding causation of cancer in human beings, and I'm just asking you to confirm this has to do with humans.
MR. GALLAGHER: Lack of foundation, and outside the scope.
A. Well, these studies' subject, yes, was tried to evaluate.
BY MR. SLATER:
Q. Cancer in human beings due to NDMA, that's what this is looking at,

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correct?
A. Looks like.
MR. SLATER: Let's go now, if we could, to the next page, please, page 22 of this article.
Q. In the top left --
MR. SLATER: Perfect, Cheryll. Thank you.
Q. In the top left, the first full paragraph it says, "There appears to be no qualitative difference between rodents and humans in the formation of DNA adducts following exposure to NDMA."
Do you remember we went through a study last night that actually talked about studying the adducts that are caused -- the DNA adducts caused by exposure to NDMA?
Do you recall we talked about that last night?
A. Yes.
Q. And that's a very important part of a mutagenic, genotoxic substance is the formation of DNA adducts as part of the process whereby somebody will eventually

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develop cancer, correct?
MR. GALLAGHER: Objection. Vague, calls for expert testimony.
A. I think it does ask for speculation. Okay. Based upon my limited knowledge, you know, once, you know, a piece of DNA, for example, was alkylated, different species, you know, they may have different defense system, okay? They can dealkylate.
So, you know, it still -- you know, you just make -- you cannot be 100 percent sure, okay, just simply because of the presence of alkylated DNA, you know. Because otherwise, you know, if what you're saying, you know, is true, then there will be no difference between, you know, you know, the mutagenicity with carcinogenicity, okay? These are the two different levels. Okay.
So you were equating those two things, you know, you know, to be the same meaning, so I don't think that that's accurate.
BY MR. SLATER:
Q. Mutagenicity is the ability to

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actually damage the DNA, leading to cancer, right?
A. That's just a potential.
MR. GALLAGHER: Objection. Calls for expert testimony.
BY MR. SLATER:
Q. I'm asking you what "mutagenicity" means. That means that something damages DNA, leading to cancer, correct?
MR. GALLAGHER: Objection. Calls for expert testimony.
A. As I said, you know, your statement is not accurate, okay. That's just a potential -- you know, you know, a potential source leading to. Because otherwise, why people or why scientists will have two different terms?
And also, you know, it's very clear, you know, you know, mutagenicity, you know, can but do not necessarily are carcinogenetic. I mean, you can -- you know, you can find it, like, in some documents, maybe even in M7 itself or some related

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document.
BY MR. SLATER:
Q. Do you know what a mutagenic, genotoxic substance is?
A. I mean, do I know some chemical part of being mutagenic?
Q. Do you know what those terms mean?
A. As I said, yeah. You know, as I said, "mutagenic" means, you know, a chemical substance will chemically react with DNA.
But whether or not, you know, that reactivity or formation of the DNA adduct either will lead to, you know, cancer, you know, that's another -- you know, another question. Okay. It may or it may not, you know.
So you trying to equating them, you know, you know, you know, the mutagenicity, you're trying to equating them, you know, to carcinogenicity, you know. This is -- you know, this is not correct.
Q. I'm actually just -- okay.

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I'll withdraw that.
When I said "I'll withdraw that," it was the first two words I said almost starting this question. Okay?
Continuing to read this, it says, "In a case of suspected NDMA poisoning in a human male, methylation of liver DNA was evident at both the N7 and O6 positions of" --
A. I'm sorry. I'm sorry. Hold on. I don't see -- I'm not seeing, you know, the paragraph that you're reading.
Q. Sure.
I'm in the left column, the first full paragraph. We just went through the first sentence. Now I'm at the second sentence.
A. The second -- oh, okay, yeah.
Q. The second sentence -- rephrase.
This paragraph continues, "In a case of suspected NDMA poisoning in a human male, methylation of liver DNA was evident at both the N7 and O6 positions of guanine," and

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it gives a citation.
Then it says, "Using an immunohistochemical technique, Parsa et al. (1987) detected the formation of 06-methylguanine in human pancreatic explants incubated in vitro with NDMA."
So those are some of the sources cited for the proposition at the beginning of the paragraph indicating there appears to be no qualitative difference between rodents and humans in the formation of DNA adducts following exposure to DNA -- NDMA.
That's what it's stating, correct?
MR. GALLAGHER: Objection to the extent it mischaracterizes the document.
A. Just by reading through, you know, you know, you know, this particular sentence, okay, it seems like -- because when you're talking about, you know, poisoning or NDMA poisoning, you know, based upon my limited knowledge, okay, it seems to be

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related to acute, you know, poisoning, which means, you know, will be extremely high, you know, levels of, you know, NDMA, okay.
So the acute poisoning, it would be different, you know, in terms of the mechanism, you know, for the -- you know, for the cause or potential, you know, you know, you know, you know, cause to cancer. You know, I think they are two different mechanisms, okay.
So, again, you know, as I said, you know, you know, the DNA adducts, you know, you know, you know, alone, you know, will not necessarily, you know, leading to, you know, cancer.
But, again, you know, I think that this will need a -- you know, a professional, you know, toxicologist, you know, to give, you know, more precise and accurate, you know, evaluation or statement.
BY MR. SLATER:
Q. To be clear as we continue to read through this article, this was an article that was cited in ZHP's deviation

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investigation report dated November 5, 2018, correct?
A. We cited particularly that table. Very specific.
Q. You cited this paper, and you cited it for that table that we looked at, right? The table about various substances and what may -- what may be the NDMA levels, remember?
That was why it was cited, right?
A. Yeah, yeah. The very reason we cited it, because of the origin of this table.
Q. What you didn't do is cite any of these other things I've been reading so far about, for example, the epidemiologic studies relating to humans developing cancer as a result of exposure to NDMA.
Those -- that part of the article wasn't cited in your deviation investigation report on the toxicological effects of having NDMA in your valsartan, right?

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MR. GALLAGHER: Objection. Foundation, and to the extent it mischaracterizes the document or --
A. Look. In that deviation report, okay, we clearly indicated, okay, NDMA, you know, you know, I think is carcinogenic to animals, okay. It's a probable, you know, carcinogenic to human. Okay.
So everything, you know, that you presented here, right, do not change the fact, okay. Even as of today NDMA is still being characterized as a Class 2A compound, which -- you know, which means, you know, as I said, it's carcinogenic to animal, and it's a probable, you know, carcinogenic to human.
So -- and another thing, you know, I also wanted to, you know, point out, you know, in terms of, you know, of these like -- you know, like you mentioned, you know, epidemiology, you know, studies, right, these were all performed in early '90s, okay?
And as I also mentioned, you know, yesterday, also maybe, you know, the

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day before, you know, we have more recent, you know, you know, epidemiological, you know, studies.
And in at least, you know, you know, some of those studies, you know, the conclusions, you know, are not consistent with the conclusion showed up, you know, in these early '90, you know, papers or studies.
MR. SLATER: Cheryll, let's scroll down just so I can get the bottom right-hand half of the page, too. No, too far. Don't try to speed us up here. A little more. Perfect. Thank you.
BY MR. SLATER:
Q. Looking now at Section 11 that's titled "Effects Evaluation," and 11.1, "Evaluation of health effects," and 11.1.1 says "Hazard identification."
Do you see that?
A. Yes, I do.
Q. In the hazard identification section, that first paragraph, it says, "Although NDMA is acutely toxic and induces

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hepatic damage in several species at dose levels of approximately 1 mg/kg body weight per day in short-term experiments, the main concern is its carcinogenicity. NDMA has been consistently shown to be a potent carcinogen in all experimental species studied."
Do you see that?
A. Yeah, experimental species, yeah, means animals, yeah.
Q. You've mentioned animal studies many times, and I think you made that point multiple times. So why haven't there been human studies done where humans have been given NDMA to see what happens to humans?
A. That would be unethical.
Q. It would be unethical, right? That's what you said?
A. Yes.
Q. Because --
A. Knowingly, yes, if you knowingly do that, yes.
Q. It would be unethical because you would know that you're likely -- well,

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rephrase.
It would be unethical because you would be increasing the risk that these people would get cancer from having the NDMA put into their body, right?
MR. GALLAGHER: Objection. Lacks foundation, and calls for expert testimony.
A. As I think I already answered that question. It's just considering the potential risk. If you knowingly to do that experiment, it will be unethical.
BY MR. SLATER:
Q. It would be unethical to knowingly give humans NDMA, correct?
MR. GALLAGHER: Objection. Calls for expert testimony.
A. I think I already made that clear.
BY MR. SLATER:
Q. And it would certainly be unethical to give humans NDMA in the levels that were found in the valsartan pills deliberately and knowingly, correct?

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MR. GALLAGHER: Objection. Calls for expert testimony, and outside the scope.
A. It's the same principle.
BY MR. SLATER:
Q. Looking now, if we can scroll down to 11.1.1.1, "Carcinogenicity" is the next section.
Do you see that?
A. Mm-hmm.
MR. SLATER: Let's scroll now to the next page, please, the left-hand column, the first full paragraph. Let's get that up. That's just the carryover paragraph. Please go down a little further. That's perfect. Okay.
Q. So -- rephrase.
In the left-hand column, the first full paragraph, I want to start in the second sentence. It says, "The weight of evidence of the carcinogenicity of NDMA in mammalian species is consistent and convincing. Moreover, the pattern of tumor

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development is characteristic of that for a mode of action of carcinogenesis involving direct interaction with genetic material. In available studies, NDMA has induced tumors in all species examined (mice, rats, hamsters), at relatively low doses in some cases, irrespective of the route of exposure," whether oral or inhalation. "Tumors were induced in a wide range of tissues, including the liver, Leydig cells, lungs, kidney, and nasal cavity, in the absence of significant non-neoplastic effects, in the limited number of studies in which these were well examined."
Do you see what I just read?
A. Yes.
Q. That language was not placed into the deviation investigation report that we were discussing a few moments ago, correct?
A. As I indicate to you, you know, by reading through, you know, this whole sentence or whatever, it's still talking about, you know, its being a carcinogen to

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animals, okay, so we clearly made that statement in the deviation report.
Q. My question is this. The language I just read is not set forth in the deviation investigation report, correct?
A. The deviation report is not intended, you know, to go into such a, you know, extensive, you know, you know, discussion, okay. So it's basically state, you know, the fact, you know, that fact, you know, is consistent, you know, with everything, you know, this report or this particular paragraph, you know, states.
Q. Let's continue.
MR. SLATER: Can you scroll down a little more, Cheryll, just to capture the bottom of the paragraph?
Q. The -- rephrase.
This first full paragraph on page 23 of this study continues, "Where it was reported, time to first tumor was relatively short. The incidence of specific tumors has been increased following administration of even a single dose or

repeated doses for short periods (i.e. 2-3 weeks); tumors have also been observed in the offspring of exposed pregnant rats and mice."

Do you see that?

A. I'm sorry, which -- which paragraph?

Q. It's the same paragraph we were just reading in --

A. Oh, okay, okay, okay, sure. Uh-huh, uh-huh.

Q. What I just read, along with the other things that I read above that, goes to the concept of this being a potent mutagenic carcinogen, correct?

MR. GALLAGHER: Objection. Vague, calls for expert testimony.

A. Again, you know, everything is talk about here is still, you know, related to animals.

MR. SLATER: Cheryl, could you scroll down so we capture the last two paragraphs in that column, please? Perfect.

Q. This article continues on

page 23, the last two paragraph -- rephrase.

Continue on page 23 of the article, the second to last paragraph in the left column says, "NDMA has been consistently mutagenic and clastogenic in human and rodent cells exposed to in vitro. Clear evidence of genetic effects has also been observed in a number of tissues from animals exposed to this substance. Notably, genotoxic effects have been observed in tissues (i.e., liver, kidney, lung) where tumors commonly arise following experimental exposure to NDMA and in germ cells."

Do you see that?

A. Yes.

Q. This continues now in the last paragraph in the left column, "DNA adducts (in particular, O6-methylguanine) formed by the methyldiazonium ion generated during metabolism likely play a critical role in NDMA carcinogenicity. Observed variations in carcinogenicity among species and strains correlate well with variations in activity of O6-methylguanine DNA-methyltransferase.

Putative pathways for the metabolism of NDMA are similar in rodents and humans, and indeed the formation of O6-methylguanine has been detected in human tissues exposed to NDMA."

You see what I just read, I assume, correct?

A. Yes.

Q. So in this article which your company cited in its deviation investigation report, they're essentially building the case for the similarities between humans and animals that are significant in determining whether NDMA causes cancer in humans; that's basically what they're discussing and building to here, correct?

A. As I said, you know --

MR. GALLAGHER: Objection, vague. Objection. Vague, calls for expert testimony, and to the extent it mischaracterizes the document.

A. Again, you know, it -- as I said, everything, you know, presented here, you know, it -- it's only, you know, indicate, you know, it's a -- it's a

carcinogenic to animals and it's a probable carcinogenic to humans.

BY MR. SLATER:

Q. Let's go up -- well, let me ask you this question before we scroll any further.

In terms of what's likely, at the levels that we've gone through in this deposition, there are some people who took the valsartan sold by ZHP that was contaminated with NDMA who will or already have developed cancer at least in part because of their exposure to that NDMA, correct?

MR. GALLAGHER: Objection. Vague, lacks foundation, calls for speculation, and calls for expert testimony.

A. This is way beyond, okay, my scope, okay. It need to be examined, or it need to be evaluated by medical doctors or, as I said, or as well as toxicologists.

BY MR. SLATER:

Q. Knowing the science available

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to ZHP, it is certainly more likely than not that at the levels of NDMA seen in the valsartan sold by ZHP, there are some people who took that who will likely or already have likely developed cancer at least in part due to that exposure to NDMA.

We don't have to argue about how many people, we don't have to argue about which cancers. But you can agree that that's happened to some people, or will, correct?

MR. GALLAGHER: Objection. Vague, lacks foundation, calls for speculation, calls for expert testimony, outside the scope, and argumentative.

A. That's your -- yeah, basically, again, that's your speculation, okay. As far as I know, this is not a fact, okay, as, you know, until -- you know, up to this point. Okay. That's your speculation.

BY MR. SLATER:

Q. Well, it's certainly likely that that will happen or has happened to some people, correct?

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MR. GALLAGHER: Objection. Vague, lacks foundation, calls for speculation, calls for expert testimony, outside the scope, and argumentative.

A. You know, as I said, I have responded multiple times. That's your speculation.

BY MR. SLATER:

Q. You would certainly agree with me that the people who took the valsartan manufactured by ZHP and contaminated with NDMA have an increased risk as a result of that exposure to develop cancer.

You'll agree with that, right?

MR. GALLAGHER: Objection. Vague, lacks foundation, calls for speculation, calls for expert testimony, outside the scope, and argumentative.

A. You know, you want me to repeat still the same answer. You know, you are making a speculation.

MR. SLATER: Let's look at the

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article, the top right-hand column of this page, page 23.

Q. Looking again at this article cited by ZHP and relied on by ZHP in its deviation investigation report, the top right column on page 23 -- do you see where I am?

A. The top right, the first paragraph?

Q. Yes.

A. Okay, yeah, I see that.

Q. It says, "Therefore, owing to the considerable evidence of carcinogenicity of NDMA in laboratory species, evidence of direct interaction with DNA consistent with tumour formation, and the apparent lack of qualitative species-specific differences in the metabolism of this substance, NDMA is highly likely to be carcinogenic to humans."

That's what this article states, correct?

A. Yeah. Based upon, you know, the last sentence, you know, you know, another way to say is NDMA, you know, is a probable, you know, carcinogen to human.

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It's still the same thing.

Q. Yeah. Probable, yeah.

A. Highly likely, you know, is probable.

So that's why, you know, as I said, IARC, you know, even as of today, you know, after what, like more than 20 years, you know, you know, after the publishing of this article, you know, it's still the same characterization as 2A, you know, Class 2A.

Q. "Highly likely to be carcinogenic to humans" means that it -- rephrase.

"Highly likely to be carcinogenic to humans" means exposure to NDMA will cause cancer in humans, correct?

MR. GALLAGHER: Objection. Vague, calls for speculation, and lack of foundation, and outside the scope.

A. See, again, you know, you just try to twist, you know, you know, the fact. Okay. You try to twist "highly likely" or, you know, you know, "probable." You know, you try to equating them to certainty, okay.

That's just not the case.
BY MR. SLATER:
Q. In medicine and in science, there's a reasonable degree of probability. You know that concept, right?
MR. GALLAGHER: Objection. Vague, calls for expert testimony, and outside the scope.
Dr. Li, to the extent you know.
A. To the extent -- yeah, there's a possibility, yeah.
BY MR. SLATER:
Q. I asked you a different question.
You understand the concept of reasonable degree of scientific probability or scientific -- rephrase.
Do you understand the concept of reasonable degree of scientific certainty?
MR. GALLAGHER: Objection. Vague.
A. Yeah. So I don't know what you're specifically try to, you know, to say or to, you know, referring to.

BY MR. SLATER:
Q. Well, I'll ask the question differently.
NDMA is highly likely to be carcinogenic to humans. That's why your company had to stop selling valsartan contaminated with NDMA, correct?
MR. GALLAGHER: Objection. Vague, lacks foundation, and outside the scope.
A. As I responded earlier, as I said, you know, to stop distribution, you know, as a responsible company it's -- you know, once, you know, the company, you know, became to know, and also, you know, after we developed the method, right, and we know the range, then we immediately, you know, you know, contact FDA. You know, so that decision, you know, was based upon, you know, this potential risk. Okay?
BY MR. SLATER:
Q. Your company stopped selling -- well, let me ask it this way.
At the levels of contamination

that we've gone through in this deposition, it would be unacceptable and, using your word, unethical to sell valsartan with those levels of NDMA contamination, correct?
MR. GALLAGHER: Objection. Vague, mischaracterizes testimony, calls for speculation, calls for expert testimony, and outside the scope.
A. You know, as I said, you know, if you knowingly do that, okay.
BY MR. SLATER:
Q. I'm sorry, what did you say?
A. As I said before, you know, if you knowingly doing that.
MR. SLATER: Thank you.
Patrick, I don't know if you have any questions. I can reserve the rest of my time, or we can conclude the deposition now.
MR. GALLAGHER: I'm happy to conclude the deposition.
MR. SLATER: Thank you very much. I'm done.

MR. GALLAGHER: Thank you.
THE VIDEOGRAPHER: The time right now is 11:17 a.m. We're now off the record.
(Whereupon, the deposition was concluded.)

CERTIFICATE

I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, MIN LI, Ph.D., was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____

MAUREEN O'CONNOR POLLARD
NCRA Registered Diplomate Reporter
Realtime Systems Administrator
Certified Shorthand Reporter
Notary Public

Dated: April 23, 2021

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, __________________________, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
Min Li, Ph.D. Date

Subscribed and sworn
To before me this
______ day of _________________, 20____.

My commission expires: _________________

____
Notary Public

LAWYER'S NOTES

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